Agreement between the Portuguese State, represented by the Ministers of Finance, Economy and Health and the Pharmaceutical Industry

The Portuguese State, represented by the Ministers of Finance, Economy and Health, and the Pharmaceutical Industry, through APIFARMA - Portuguese Pharmaceutical Industry Association, represented by its President and Vice-President of the Board, hereinafter jointly referred to as Parties, agree to implement the measures provided for in this Agreement to contribute to the sustainability of the National Health Service (NHS), to ensure access to medicines and to enhance the attractiveness of conditions for investment in Portugal.

Considering:

The framework of the XXI Government Program in the Health area, aimed at creating a favorable environment among all the sector's players to the protection of health, in order to increase NHS efficiency for the available resources and, in the medicines' sector, to promote a sustainable policy in order to reconcile budgetary rigor with access to therapeutic innovation;

The concordance with the strategic guidelines of the Commitment to Sustainability and Development of the National Health Service between 2016 and 2018, signed by the parties;

The decrease in the average level of the medicines' price in Portugal in recent years, which was reflected in the reduction of attractiveness for investment;

The importance of continuing to ensure a convergence of efforts between public institutions and economic agents, so that the national effort to control public expenditure allows the maintenance of high standards of accessibility of patients to treatment better, and the provision, tend to be free of health care to citizens;

The importance of continuing to ensure a convergence of efforts between public institutions and economic agents, so that the national effort to control public expenditure allows the maintenance of high standards of accessibility of patients to the best treatments, as well as the provision of tendentiously free healthcare to citizens;

The value of improving the organization of the market, both in terms of ease of access of citizens to prescribed therapies, and of access to innovative medicines, under the rules established in SiNATS (Decree-Law No. 97/2015 of 1 June and other regulatory legislation);

The importance of the extended effort, shared by the State and by the economic and social agents, for the development of programs within the rational use of medicines, adherence to therapy and the contest to non-compliant ethical practices, allowing the focus on prevention and primary healthcare, counting with the intervention of the pharmaceutical industry;

The need to introduce improvements in the structural rules of the market in terms of dispensing channels of medicines, of the review of the instruments of access to medicines, including the reimbursement system, and of medicine's public funding policies;

The availability of the pharmaceutical industry, represented by APIFARMA, to maintain cooperation with the Portuguese State through a financial contribution to ensure the sustainability of the NHS, allowing control over the evolution of public expenditure on medicines and patients' access to new innovative therapies, with prices resulting from the existing legal mechanisms and market entry deadlines that comply with the law in force;

The importance of considering spending support mechanisms in the medicine's policy, both through the efficient use of resources, such as the consideration of exceptional procedures for resource allocation due to extraordinary situations, temporally defined, involving risk-sharing mechanisms;

The importance of achieving, in the medium-term, the benchmark for public spending on medicines in order to create sustainable conditions that generate the share of gains between the State and the agents of the sector;

The importance of ensuring a predictable framework for all agents of the medicine's sector to create a favorable institutional environment for investment, for R&D and innovation, as well as for building productive, scientific and commercial capacities based in Portugal.

The Parties agree and write the following:

Clause 1

Subject

1. This Agreement regulates the terms and conditions under which the Portuguese State, represented by the Ministers of Finance, Economy and Health, on one hand, and the Pharmaceutical Industry, represented by APIFARMA, on the other hand, by adherence of the Pharmaceutical Industry companies, as provided in Clause 4, undertake to achieve the budgetary targets for 2016 of public NHS expenditure on medicines in outpatient setting, including subsystems, and hospital setting, to ensure the sustainability of the National Health Service.
2. This Agreement provides for a medium-term understanding, covering the time period until the end of 2018.

Clause 2

Public expenditure on medicines

1. For the purposes of compliance with this Agreement, a referential is set for 2016 for public expenditure with medicines of 2.000 million euro, according to data provided by INFARMED – the National Authority of Medicines and Health Products, I.P. (INFARMED, I.P.).

2. For the years 2017 and 2018, the goal of public expenditure with medicines will be set, with a reference value that will determined, after consultation with APIFARMA, by the Ministry of Health.

3. For purposes of the preceding paragraph, and taking into account the necessary NHS sustainability conditions, the benchmark for medium-term public spending with medicines should be tendentiously adjusted, considering the annual growth rate of the Gross Domestic Product.

Clause 3

Financial contribution of the Pharmaceutical Industry for the year 2016

1. The Pharmaceutical Industry, in a cooperative effort with the Portuguese State, accepts to collaborate on a contribution to the control of public expenditure on medicines in the year 2016, through a financial contribution amounting to 200 million euro.

2. Notwithstanding the previous paragraph, the total contribution of APIFARMA's member companies adherent to the Agreement, which corresponds to the sum of the contributions of each company, has a minimum value of 150 million euro, being APIFARMA incumbent to determine the formula of financial contribution of its member companies adherent to the Agreement.

3. Companies adherent to the Agreement non-members of APIFARMA should in 2016 and upon adherence, collaborate in the expenditure reduction goal referred to in the preceding paragraph through a contribution according to the calculation methodology to be set by INFARMED, I.P..

4. If APIFARMA's member companies adherent to the Agreement are representative of a share of more than 75% of the total costs of the NHS (outpatient and hospital), the contribution shall be increased by the amount proportional to that share.

5. Research and Development expenses referred to in paragraphs 3 and 4 of Article 5 of Decree-Law no. 23/2004, of 23 January, shall be deducted from the amount of the individual contribution of the adherent companies to this Agreement, as well as the investments directly required for the implementation of the procedures of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 in the context of the fight against counterfeit medicines, as well as the industrial investments for reinforcement of productive base, in terms to be regulated by Order from the member of the government in the health area.

6. The Monitoring Committee, provided for in Clause 12, regularly monitors the market, based on data provided by INFARMED, I.P., in order to check the evolution of the public expenditure on medicines in regards to the goal mentioned in the previous Clause and to determine the immediate implementation measures to control it, if necessary.

7. If the value of the public expenditure on medicines, provided for in the previous Clause, is exceeded, according to the information from INFARMED, I.P., the adherent companies to this Agreement shall pay the amount that exceeds the maximum goal set during the first quarter of 2017. Notwithstanding the provisions in paragraphs 2 and 4, APIFARMA's member companies adherent to the Agreement shall only be responsible for the part attributable to them in the increase of the public expenditure on medicines in the NHS, according to the proportion of the respective market share, up to the limit that would result

from the application of Law No. 159-C/2015, of 30 December (Extension of revenue provided in the State Budget for 2015).

8. The investment allocated to specific programs of public initiative which may include medicines that have the characteristics which give them exceptional character on the elimination of certain diseases, should not be taken into account for the purposes of the preceding paragraph, about the value of public expenditure on medicines.

Clause 4

Adhesion by the companies of the Pharmaceutical Industry

1. The adherence to this Agreement, by each company holder of marketing authorizations for marketed medicines, legal representative or responsible for commercialization, is formalized through an unambiguous written declaration for that purpose, without exceptions or reservations.

2. The declaration provided for in the previous paragraph is signed by the natural person holder of the adherent company or by whom is empowered to bind the legal person holder of the adherent company, and in this case the signature should be properly acknowledged with mention of this capacity.

3. APIFARMA shall deliver to INFARMED, I.P., the declarations of adherence of its member companies pursuant to the previous paragraphs. Non-members of APIFARMA shall send their declaration of adherence to INFARMED, I.P..

4. This Agreement only binds the Parties and the adherent companies after the adherence to it of a number of companies, members of APIFARMA, representative of a minimum of 75% of the share of NHS total expenditure (outpatient and hospital).

5. The deadline for adherence is 30 days after the date of signature of this Agreement.

Clause 5

Regularization deadlines of Pharmaceutical Industry's contribution for the year 2016

1. The adherent companies to this Agreement undertake, in proportion to their market share in 2016, to pay:
   a) 30% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by payment to the Central Administration

of the Health System, I.P., (hereinafter ACSS, I.P.) until April 15th 2016. The contribution to be made results from the amounts invoiced by each adherent company within the NHS in 2015.

b) 20% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by payment to ACSS, I.P., until June 30th 2016. The contribution to be made results from the share of amounts invoiced by each adherent company within the NHS from January 1st to March 31st 2016.

c) 30% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by payment to ACSS, I.P., until September 30th 2016. The contribution to be made results from the amounts invoiced by each adherent company within the NHS from January 1st to June 30th 2016.

d) 20% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by payment to ACSS, I.P., until December 31st 2016. The contribution to be made results from the amounts invoiced by each adherent company within the NHS from January 1st to September 30th 2016.

2. The parties shall share the necessary information for the validation of the expenditure final values, as well as information with a level of detail appropriate to the application of the respective contribution formulas.

3. Notwithstanding the provisions of Clause 12, INFARMED, I.P. is responsible for the calculation based on the data available of the market share, and ACSS, I.P. is responsible for monitoring of the entire process associated with the payment of the contributions provided for in previous paragraphs by the adherent companies to this Agreement, after consulting with the Monitoring Commission.

Clause 6

Hospital debts payment

1. The Ministry of Health commits to support the NHS institutions with the necessary actions to continue to proceed with payment of total debt from hospital supplies of medicines and in vitro diagnostics by the adherent companies to this Agreement prior to 31 December 2014, and to ensure that the value of the hospital debt by 31 December 2016 is lower, in each adherent company, than the value calculated on 31 December 2014 and/or 31 December 2015, depending on the lower value.

2. For the purposes of the preceding paragraph, the payments to be made should take into account market developments and be adjusted in proportion.
3. The Ministry of Health is committed, in conjunction with the Ministry of Finance, to develop the necessary actions to proceed to the regularization of arrears, as well as to proceed with the necessary measures for the implementation of the provisions of Decree Law No. 62 / 2013 of 10 May on late payments.
4. The Monitoring Committee shall make a quarterly evaluation of payments, according to matrix to be consensually agreed, globally and per company, in order to assess the development of the payment of contributions under this Agreement and the corresponding evolution of the settlement of arrears, as well as to present proposals that, in this context, are considered appropriate.

Clause 7

Marketing authorization of innovative medicines

The Ministry of Health commits to promote conditions for patients' access to medicines that are demonstrated to be innovative, particularly by complying with decision and evaluation deadlines provided by law, by adopting innovative contracting methodologies, namely shared risk management systems, and by recognizing the specificity of certain medicines, namely orphans and those aimed at specific populations, provided for in Decree-Law No. 97/2015, of 1 June.

Clause 8

Implementation of measures to control public expenditure

1. The Ministry of Health is committed to evaluate the referencing price mechanism of reimbursed medicines, considering the European Union prices dynamics and the definition of the reference countries, considering geographical proximity criteria, market structures and epidemiological characteristics, if there is a context of economic growth and if the NHS sustainable conditions are assured.

2. The Ministry of Health is committed to implement changes in the framework of the price system of non-reimbursed prescription medicines through a scheme of notified prices.

3. The Ministry of Health is committed to assess, during the duration of this Agreement, in collaboration with the different medicine's chain stakeholders, the efficiency mechanisms in public spending, considering the following measures:

a) Implementation of the annual medicines reviews based on international referencing rules, with the possible use of a brake mechanism in case price changes result in a decrease higher than 10%;

b) Change in medicines dispensing rules dispensed in outpatient hospital setting, extending its dispensing to community pharmacies;

c) Integration of the evaluation of health technologies results in the preparation of Clinical Orientation Standards for efficient use of health resources and technologies.

4. The Ministry of Health is committed to establish a review system of the legal framework for public reimbursement of medicines with the broad participation of the economic and social agents involved.

Clause 9

Reduction of administrative costs and the sustainability of the medicine's chain

1. The Ministry of Health is committed to promote the adoption, in coordination with other Ministries, of measures to ensure an effective administrative costs reduction, particularly regarding the revision of the legislation on the medicine's packs retail price and the application of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 concerning the fight against counterfeit medicines.

2. The Ministry of Economy is committed to create a working group with other Ministries and with other medicine's sector associations in order to promote the development of the Pharmaceutical Industry in Portugal, strengthening the economic protection of the sector's agents, namely by the reinforcement or creation of instruments to promote the national added value, to expand the investment in production and in R&D in Portugal, considering their inclusion for this Agreement's purposes, to improve the competition regulation instruments, the public markets operation and the promotion of the sustainability of the medicine's sector agents.

Clause 10

Legislative and administrative stability

The Ministry of Health will promote the maintenance of a stable legislative and regulatory framework throughout the duration of this Agreement, particularly in relation to the regulation of medicines prices, notwithstanding of the amendments and the legislative and regulatory adjustments deemed necessary and appropriate for the NHS sustainability or to ensure the compliance with international commitments of the Portuguese State, in line with the objectives under this Agreement, in an appropriate institutional dialogue framework with APIFARMA, and with the legislative and regulatory initiatives to be the subject to appropriate impact assessment studies.

Clause 11

Deductibility of the Pharmaceutical Industry contributions

The deductibility of financial contributions that may be provided by Pharmaceutical Industry companies under this Agreement, for purposes of corporate income tax, shall be determined in accordance with applicable tax laws.

Clause 12

Monitoring the Agreement implementation

1. The implementation of this Agreement shall be accompanied by a commission composed of representatives of the Ministry of Finance, the Ministry of Economy, the Ministry of Health and APIFARMA, in terms to be defined by joint Order of the members of the Government concerned.

2. It is competence of the Monitoring Commission to rule on technical issues that may arise in the implementation of this Agreement, insofar as this is requested by the signatory entities, and to propose initiatives conducive to the proper development of the objectives set in this Agreement.

3. The Monitoring Commission meets monthly to assess the suitability of this Agreement to market developments, particularly in terms of achieving the budgetary objectives of expenditure on medicines, and monitoring the economic environment of the product value chain and shall submit bimonthly reports results with the results obtained, which will be sent to the signatory entities.

4. The Monitoring Commission shall draw up an annual implementation report in order to the signatory entities can make an assessment of the results achieved and adjustments of the terms of this Agreement which may arise.

Clause 13

***Force majeure* and change of circumstances**

Should there occur any extraordinary and/or unforeseeable circumstances, resulting in an exceptional increase in the prescription and sale of reimbursed medicines and hospital medicines in the NHS context (namely, exceptional circumstances relating to the prevalence or incidence of pathologies, e.g. epidemic surges), the increase in NHS expenditure relating to reimbursement or purchase of medicines resulting therefrom shall not be taken into account for the purposes of determining the growth in the State's expenditure and determining the Pharmaceutical Industry's contribution, in the terms of this Agreement.

Clause 14

Termination

1 – The absolute and final non-compliance by either Party of its commitments resulting from this Agreement, including the adoption of measures that counter the conditions of this Agreement, entitles the non-compliance party to terminate it.

2 – It is considered absolute and final the non-compliance that persists after two written interpellations of the non-defaulting Party.

Clause 15

Coming into force

This Agreement shall take effect from the date of its signature.

Lisbon, 15th March 2016

By the Ministry of Finance,
The Minister of Finance

(Mário Centeno)

By the Ministry of Economy,

The Minister of Economy

(Manuel Caldeira Cabral)

By the Ministry of Health,

The Minister of Health

(Adalberto Campos Fernandes)

By APIFARMA – Portuguese Pharmaceutical Industry Association

The President of the Board	The Vice-President of the Board
(João Almeida Lopes)	(Eduardo Pinto Leite)