

Agreement between the Ministries of Finance and of Health and the Pharmaceutical Industry

The Ministries of Finance, represented by the Minister of State and of Finance, and of Health, represented by the Minister of Health, and the Pharmaceutical Industry, through APIFARMA – the Portuguese Association of Pharmaceutical Industry, represented by its President and Vice-President of the Board, hereinafter jointly referred to as Parties, agree to implement the measures provided in this Agreement in order to contribute to the sustainability of the National Health Service (NHS) and to ensure access to medicines.

Considering:

The legislative and regulatory stability assumed in the Agreement signed on 14 May 2012 and the maintenance of the need to ensure the budgetary and financial sustainability of the NHS, namely by the adjustment of public expenditure on medicines to the average standards of the European Union countries, while maintaining the stability achieved by the Program for Economic and Financial Adjustment agreed between the Portuguese State, the European Commission, the International Monetary Fund and the European Central Bank;

The importance of continuing to ensure a convergence of efforts between public institutions and economic agents, so that the national effort to reduce public expenditure allows the maintenance of high standards of patient access to the best therapeutics, as well as a tendentially free provision of health care to citizens;

That the Pharmaceutical Industry, represented by APIFARMA, is available to maintain the collaboration with the Portuguese State through a financial contribution in order to ensure the sustainability of the NHS and patients' access to new therapeutics;

The importance of continuing to ensure, in a context of sustained reduction of public expenditure on medicines, the maintenance of patient access to innovative products, at prices resulting from the existing legal mechanisms and in timeframe that comply with the law in force;

The Parties agree and write the following:

Clause 1

Subject

This Agreement regulates the terms and conditions under which the Ministries of Finance and of 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 2015 of NHS public expenditure on outpatient,

including subsystems, and hospital medicines, to ensure the sustainability of the National Health Service.

Clause 2

Public expenditure on medicines

For the purposes of compliance with this Agreement, it is set for 2015 a goal of public expenditure on medicinal products of 2 billion euro, according to the data provided by INFARMED – the National Authority of Medicines and Health Products, I.P. (INFARMED I. P.).

Clause 3

Financial contribution of the Pharmaceutical Industry for the year 2015

1 – The Pharmaceutical Industry, in an additional cooperation effort with the Portuguese State, agrees to collaborate in a reduction of the public expenditure on medicines in 2015 upon a contribution in the amount of 180 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 contribution of each company, has a minimum value of 135 million euro, being APIFARMA incumbent to determine the formula of financial contribution from its member companies adherent to the Agreement.

3 – Companies adherent to the Agreement non-members of APIFARMA accept, in 2015 and by adherence, to collaborate in the expenditure reduction goal referred to in the preceding paragraph upon a contribution considering the total sales by type of product according to the calculation methodology to be set by INFARMED.

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, in accordance with the law

6 – The Monitoring Committee, provided for in Clause 13, 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 2016. 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.

Clause 4

Pharmaceutical Industry companies' adherence

1 – The adherence to this Agreement, by each company holder of marketing authorizations for marketed medicines, 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.

4 – This Agreement only binds the Parties and the adherent companies after the adherence to it of a number of companies 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 2015

1 – The adherent companies to this Agreement undertake, in proportion to their market share in 2015, to pay:

- a) 25% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by bank transfer to the Central Administration of the Health System, I.P., (hereinafter ACSS, I.P.) until March 31st 2015. The contribution to be made results from the amounts invoiced by each adherent company within the NHS in 2014.

- b) 25% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by bank transfer to the ACSS, I.P., until June 30th 2015. The contribution to be made results from the proportion of the amounts invoiced by each adherent company within the NHS by March 31st.
- c) 25% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by bank transfer to ACSS, I.P., until 30 September 2015. The contribution to be made results from the amounts invoiced by each adherent company within the NHS by June 30th.
- d) 25% of the amount resulting from the application of Clause 3, paragraph 2, by issuing credit notes in favour of NHS hospitals and/or by bank transfer to ACSS, I.P., until December 31st 2015. The contribution to be made results from the amounts invoiced by each adherent company within the NHS by September 30th.

2 – The parties will 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 13, ACSS, I.P., is responsible for the calculation of the market share, based on data from INFARMED, I.P., and of the respective contributions mentioned in the previous paragraphs, as well as for monitoring and reporting the entire process associated with the payment of said contributions by the adherent companies to this Agreement, after consulting with the Monitoring Commission.

Clause 6

Hospital debts payment

The Ministry of Health commits to make every effort to continue to proceed with the payment of the total debt regarding hospital supplies (the supply of medicines to NHS hospitals) by adherent companies to this Agreement prior to 31 December 2013, and to ensure that the value of the hospital debt by 31 December 2015 is lower, in each adherent company, than the value calculated on 31 December 2014.

Clause 7

***In Vitro* Diagnostics**

The Ministry of Health commits to make every effort to continue to proceed with the payment of the total debt regarding *in vitro* diagnostics hospital supplies (the supply of products for use in *in vitro* diagnostics to NHS hospitals) prior to 31 December 2013.

Clause 8

Marketing authorization of Innovative Medicines

The Ministry of Health commits to promote conditions for patients' access to medicines that demonstrate to be innovative, particularly by complying 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.

Clause 9

Pricing scheme for non-reimbursed prescription medicines

The Ministry of Health commits to achieve the legislative process that allows non-reimbursed prescription medicines to start following a notified price system, allowing a limited price variation, in a percentage to be set annually by INFARMED, I.P., after consulting with APIFARMA.

Clause 10

Reduction of administrative costs

The Ministry of Health commits to promote the adoption, in conjunction with other Ministries, of measures to ensure an effective reduction of administrative costs, particularly with regard to the revision of legislation about the retail price of medicines packages, in a way to promote the development of the Pharmaceutical Industry in Portugal.

Clause 11

Legislative and administrative stability

The Ministry of Health will promote the maintenance of a stable legislative and regulatory framework for 2015, particularly in relation to the regulation of medicines prices, without prejudice of the amendments and the legislative and regulatory adjustments deemed necessary and appropriate to the NHS sustainability.

Clause 12

Deductibility of 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 13

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 Health and APIFARMA, in terms to be defined by Joint Order of the Government members 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 defined in this Agreement.

3 – The Monitoring Committee 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 shall submit bimonthly reports with the results obtained, which will be sent to the signatory entities.

Clause 14

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 15

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 16

Coming into force

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

Lisbon, 21 November 2014

By the Ministry of Finance,
The Minister of State and of Finance

(Maria Luis Albuquerque)

By the Ministry of Health,
The Minister of Health

(Paulo Moita de Macedo)

By APIFARMA – Portuguese Association of the Pharmaceutical Industry,
The President of the Board The Vice-President of the Board

(João Almeida Lopes)

(Eduardo Pinto Leite)