

## **Agreement between the Ministry of Health, Ministry of Economy and Employment, Ministry of Finance and the Pharmaceutical Industry**

The Ministry of Finance, represented by the Minister of State for Finance, the Ministry of Economy and Employment, represented by the Minister of Economy and Employment, the Ministry of Health, represented by the Minister of Health, and the Pharmaceutical Industry, through APIFARMA – Portuguese Association of Pharmaceutical Industry, represented by its President, 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 necessary budgetary and financial sustainability of the National Health Service (NHS), namely by the adjustment of public expenditures on medicines to the average standards of the European Union countries, as stated in the financial adjustment program agreed between the Portuguese Government, the European Union, the International Monetary Fund (IMF) and the European Central Bank (ECB);

The importance of ensuring 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 the provision of a tendential free health care to the citizens;

That the Pharmaceutical Industry, represented by APIFARMA, is available to make an additional financial contribution to ensure the sustainability of the NHS and patients' access to new therapeutics;

The measures already taken by the Government, particularly through the Decree-Law no. 112/2011 of 29 November, on changing the price system, establishing new reference countries for the pricing of medicinal products marketed in Portugal, reduction of marketing margins and lower prices for generic medicines to be marketed;

The initiatives taken in the field of industrial property, through the creation and installation of a specialized court of intellectual property, as well as the creation of a specific mechanism for settlement of disputes arising out of industrial property rights when reference medicines and generic medicines are at stake, through the necessary arbitration;

The need to improve the negotiation mechanisms of pharmaceutical supplies to hospitals, under the law, in the context of procedural transparency, the equity in patient access to medicines, the compliance with the clinical guidelines developed by scientifically competent authorities and the free competition among market operators ;

The importance of ensuring, in a context of sustained reduction of public expenditure on medicines to levels similar to the average of European countries, 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 importance of promoting the sustainability of economic activities associated with the medicine's value chain, in order to boost investment and the dynamics of innovation, to promote qualified employment;

The need to create a stable regulatory framework that serves as a reference for economic agents, but without jeopardizing the possibility of introduction of legislative and regulatory adjustments that are considered necessary and appropriate.

The parties agree and write the following:

**Clause 1**  
**Purpose or Subject**

This agreement revises and replaces the Protocol signed on 16 March 2011 between the Ministry of Health, the Ministry of Finance, the Ministry of Economy, Innovation and Development and the Pharmaceutical Industry, represented by APIFARMA.

**Clause 2**  
**Scope**

This Agreement regulates the terms and conditions under which the Ministries of Finance, represented by the Minister of State for Finance, Economy and Employment, represented by the Minister of Economy and Employment, and Health, represented by the Minister of Health and the Pharmaceutical Industry, by the adhering companies whose instrument of accession are deposited at INFARMED as provided in Clause 9<sup>th</sup> of this Agreement, are committed to the achievement of the budgetary targets for 2012 and 2013 with ambulatory and hospital pharmaceutical expenditure .

**Clause 3**  
**Financial Goals**

1 – In global terms, it is set for 2012 a goal of public expenditure included in the State Budget for 2012 with medicines in the National Health Service (NHS) of 1.25% of GDP170 billion euro.

2 – Companies that will firm this Agreement, in an additional cooperation effort with the Portuguese State, agree to collaborate in a reduction of expense in the amount of **300 million euro**, compared with the figures of 2011, that correspond to **170 million euro for the hospital market** and **130 million euro for the outpatient market**.

3 - Notwithstanding the amount of reduction on the previous paragraph, the partial values deemed to be met provided that they have a variation in the opposite direction not exceeding 10 million euro.

4 - For 2013 is fixed a goal of public expenditure on medicines in the National Health Service (NHS), whose reference value is determined by the Ministry of Health in

accordance with the commitments made by the Government under the Program Economic and Financial Assistance (PAEF).

#### **Clause 4**

##### **Expenditure Control**

1 - The goal of public expenditure with medicines defined in Clause 3<sup>rd</sup> for 2012 is set at **2.038 million euro, 842 million euro for hospital market and 1.196 million euro for outpatient market.**

2 - For 2013, the goal of public spending with medicines will be set by the Ministry of Health in accordance with the commitments made by the Government under the Program for Economic and Financial Assistance (PAEF).

#### **Clause 5**

##### **Contribution of the Pharmaceutical Industry for the containment of medicines expenditure**

1 - In the context of this Agreement, the Pharmaceutical Industry is committed to collaborate with the Portuguese State in the effort for sustainability of public expenditure with medicines in 2012 and 2013, upon payment of a contribution to be provided by member companies, in the amount that exceeds the public expenditure objectives on medicinal products as defined in Clause 4<sup>th</sup>.

2 - If the objectives of public expenditure with medicines in the NHS included in the State Budgets for 2012 and 2013 and provided in Clause 4<sup>th</sup> are achieved, there will be no contribution from the pharmaceutical industry, even though the decrease in public expenditure in the hospital market or in the outpatient market is less than the predicted values in that Clause.

3 - The mechanisms of the breakdown of contributions by the Pharmaceutical Industry companies and the criteria for deduction of R&D will be specified at the time of accession of the companies, under Clause 9<sup>th</sup>, and will be part of this Agreement.

## **Clause 6**

### **Creating a Fund by the Pharmaceutical Industry for hospital expenditure**

1 – Pharmaceutical Industry Companies involved in this Agreement are compromised to create a financial fund in a bank to be designated, corresponding to 2% of NHS monthly turnover of each company, measured at the end of each month.

2 - If the expenditure with hospital medicines is not controlled as provided in Clauses 3<sup>rd</sup> and 4<sup>th</sup> of this Agreement, the Monitoring Committee established in Clause 20<sup>th</sup> may recommend the increase of the financial Fund up to 4%.

3 - The Monitoring Committee will monthly review the value of the Fund and financial market developments of medicines marketed in order to achieve the preceding paragraph, committing companies to submit a quarterly report with net sales by Hospital, in order to determine the actual NHS hospital medicines expenditure .

4 - The Fund will aim the contribution of companies that will signed this Agreement in reducing the hospital medicines expenditure, in the case of the objectives of reducing public expenditure on medicines marketed in hospitals contained in Clause 4<sup>th</sup> are not achieved.

5 - The terms of operational expenditure reduction of hospitals with medicines will be set by the Central Administration of the Health System (ACSS).

6 - If there is no place for payment of contributions, benefits made by companies will be returned in full, plus bank interest that have expired.

7 - The creation, management and use of the fund will be jointly defined by Ordinance of the Minister of Health and Minister of State for Finance, in compliance with the principles of this Clause.

## **Clause 7**

### **Creating a Fund by the Pharmaceutical Industry for outpatient market**

1 – Pharmaceutical Industry Companies involved in this Agreement are compromised to create a financial fund in a bank to be designated, corresponding to 2% of NHS monthly turnover of each company, measured at the end of each month.

2 - If the expenditure with the outpatient market is not controlled as provided in Clauses 3<sup>rd</sup> and 4<sup>th</sup> of this Agreement, the Monitoring Committee established in Clause 20<sup>th</sup> may recommend the increase of the financial Fund up to 4%.

3 - The Monitoring Committee will monthly review the value of the Financial Fund and market trends in the outpatient medicines marketed in order to achieve the previous paragraph.

4 - The Fund will aim the contribution of companies that will signed this Agreement in reducing the expenditures on ambulatory medicinal products, in the case of the objectives of reducing public expenditure on ambulatory medicinal products contained in Clause 4<sup>th</sup> are not achieved.

5 - If there is no place for payment of contributions, benefits made by companies will be returned in full, plus bank interest that have expired.

6 - The creation, management and use of the fund will be jointly defined by Ordinance of the Minister of Health and Minister of State for Finance, in compliance with the principles of this Clause.

## **Clause 8**

### **Hospital Debts Payment**

1 – Regarding the payment of hospital supplies, the Ministry of Health commits to:

- a) Create mechanisms that allow the debts payment accounted for and due on 31<sup>th</sup> of December of 2011 on hospital supplies of medicines and diagnostics in vitro won more than 180 days, as follows:
  - i) A payment of 20% achieved in the first half of 2012;
  - ii) A payment of 40% during the second half of 2012, and
  - iii) the remaining debt paid off later;
- b) Create the conditions for central payment, with the coordination of the process through the Central Administration of the Health System (ACSS).
- c) Efforts towards the fulfilment of the timeliness of payment by the institutions of the National Health Service.

2 - The Ministry of Health is committed to create the necessary conditions for full compliance with and enforcement of payment of the hospital debts and the timeliness of payment.

3 - Regarding the payment of hospital supplies, APIFARMA commits to endeavour next to its associates, to found non-judicial ways for the resolution of interest on arrears charging processes brought in relation to establishments of the NHS.

### **Clause 9**

#### **Pharmaceutical Industry companies' Joining**

1 - Each company holding a marketing authorization for medicinal products can adhere to this Agreement by formalizing a written and unequivocal declaration to that effect, without reservation or exception.

2 - The statement referred to above is signed by a natural person holder of the member company or by whom has the legal power to force the legal person holder of the member company, and in this case, the signature must be authenticated as duly authorized.

3 - APIFARMA will deliver to INFARMED the statements of compliance pursuant to the preceding paragraphs.

### **Clause 10**

#### **Ministry of Health Commitments**

The Ministry of Health commits to observe the implementation of the measures listed in the Program for Economic and Financial Assistance (PAEF):

- a)* Promote conditions for patient access to medicines that demonstrate to be innovators , namely through fulfilment of the evaluation and decision timelines defined in the law;
- b)* Consider, under the law on public procurement and public expenditure, the mechanisms for the negotiation of pharmaceutical supplies to hospitals, the transparency of procedures, equity in access to medicines for patients, respect for the best evidence scientific advice and recommendations or rules issued by the competent official bodies and free competition among market participants;

- c)* Monitor and evaluate, in collaboration with the Ministry of Justice, the implementation of Law no. 62/2011 of 12 December;
- d)* Develop initiatives to simplify procedures that promote economic initiatives in the pharmaceutical industry sector, to strengthen its role in improving the welfare of citizens, promoting investment, innovation, employment and exports.

### **Clause 11**

#### **Legislative Stability**

Ministries of Economy, Employment and Health will promote the maintenance of a stable legislative and regulatory framework, in particular regarding the regulation of medicine prices, subject to the amendments and the legislative and regulatory adjustments that are considered necessary and appropriate to the sustainability of NHS.

### **Clause 12**

#### **Commitments of the Ministries of Economy and Employment and Health**

The Ministries of Economy and Employment and of Health will endeavour to:

- e)* Ponder the review of pricing methodology of medicines for human use in order to provide that non-reimbursed prescription medicines will obey to a notified price system, but subject to a price formation scheme with reference prices of a set of countries defined by the Government;
- f)* Promote the creation of conditions to foster research and development in Portugal in the area of medicines, particularly through the development of clinical trials;
- g)* Strive for the establishment of partnerships with public bodies and associations, to establish a plan to support the competitiveness and internationalization of Portuguese companies and export promotion;
- h)* Develop initiatives that allow for the combat to counterfeit medicinal products, the illegal export of medicines and anticompetitive business practices.



### **Clause 13**

#### **Revision of prices of medicines for human use**

The Ministries of Economy and Employment and of Health commit to proceed to the repeal of Ordinance no. 1041-A/2010 of 7 October, in order to incorporate the 6% deduction in the revision of prices of 2013.

### **Clause 14**

#### **Implementation of measures by the Pharmaceutical Industry**

In the scope of this Agreement, the Pharmaceutical Industry assumes the following obligations:

- a)* To contribute to the reduction of NHS' expenditure with medicines;
- b)* To assist with the implementation of measures for the rational use of medicines.

### **Clause 15**

#### **Reduction of administrative costs**

1- For the purposes of this Agreement, "administrative costs" shall mean the actions or omissions that, while not being attributable to the investor, its business or its organization, impair the activity of companies and are rooted in acts of public administration

2 – The Ministry of Health commits to endeavour, in conjunction with other Ministries, for the reduction of administrative costs, particularly as regards the eventual revision of legislation on the Retail Price of medicinal products' packaging, in order to promote the development of the pharmaceutical industry in Portugal.

### **Clause 16**

#### **Access to Innovation**

The Ministry of Health, in partnership with the Pharmaceutical Industry, commits to create conditions for better patient access to medicines which constitute well demonstrated therapeutic innovation, notably through the adoption of innovative contracting methodologies, including risk-sharing management systems, and the recognition of the specificity of certain medicinal products, including orphans and those aimed at specific populations.

## **Clause 17**

### **Development of clinical trials in Portugal**

1 – The Ministries of Economy and Employment and of Health recognise the strategic importance of clinical research, in partnership with the Pharmaceutical Industry, to the improvement of healthcare in Portugal.

2 – The promotion of clinical trials in Portugal takes into account the European Union legislation and applicable national rules, in whose preparation or implementation APIFARMA will be consulted.

## **Clause 18**

### **Understanding Platform**

1 - There shall be a platform between APIFARMA and the Ministries of Finance, Economy and Employment and Health for the implementation of this Agreement.

2 – Under the platform to be established in terms of the preceding paragraph, a Strategic Plan shall be prepared for development of the Medicinal Products area and the recognition of the Pharmaceutical Industry as a strategic sector.

## **Clause 19**

### **Recognition of contributions of the Pharmaceutical Industry as tax deductible**

The recognition as a fiscal cost of the financial contributions that may be provided by the companies of the Pharmaceutical Industry under this Agreement shall be made in accordance with the applicable tax laws

## **Clause 20**

### **Monitoring of performance of the Agreement**

1 – For the purposes of implementation and monitoring of this Agreement, a Monitoring Committee is created and shall comprise one representative of the Ministry of Finance, two of the Ministry of Economy and Development, three of the Ministry of Health, one of whom shall preside, and three of the Pharmaceutical Industry, although the Ministry of Health and the Pharmaceutical Industry may also designate up to two alternates, each.

2 – The Monitoring Committee shall, in addition to other duties under this Agreement, issue an opinion on any technical matters arising from performance of this Agreement, to the extent requested by the Parties, and suggest initiatives conducive to the proper development of the commonly accepted goals of this Agreement.

3 – The Monitoring Committee of the Agreement meets monthly to assess the suitability of this Agreement to market developments, particularly in terms of achieving the objectives of budgetary expenditure on medicines, and present bimonthly reports of the results obtained, which will be sent to the signatory entities.

4 – The Ministry of Health, after consulting with the Monitoring Committee of the Agreement, and if the goals of expenditure reduction are not being met, shall adopt additional measures to control expenditure reduction, in order to comply with the requirements in Clauses 3<sup>rd</sup> and 4<sup>th</sup> of this Agreement.

## **Clause 21**

### **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 medicinal products reimbursed in the context of the NHS (namely, exceptional circumstances relating to the prevalence or incidence of pathologies, e.g. epidemic surges, and significant changes to the legal framework), the increase in the NHS' expenditure relating to reimbursement or purchase of medicinal products 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 22**

### **Termination**

1 - The absolute and final default, by either Party under its commitments resulting from this Agreement, including measures that counter the conditions of this Agreement, shall entitle the non-defaulting 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 23**

**Amendments**

Any amendments hereto shall be subject to a written agreement signed by the Parties, to which companies shall join under the terms of Clause 9<sup>th</sup>.

**Clause 24**

**Coming into force**

The Agreement shall be effective during the years of 2012 and 2013.

Lisbon, May 2012

**By the Ministry of Health,**

The Minister of Health

(Paulo Moita de Macedo)

**By the Ministry of Finance,**

Minister of State for Finance

(Vitor Louçã Rabaça Gaspar)

**By the Ministry of Economy and Employment,**

By the Minister of Economy and Employment, on behalf

The Secretary of State of Entrepreneurship, Competitiveness and  
Innovation

(Carlos Nuno Oliveira)

**By APIFARMA, Portuguese Association of Pharmaceutical Industry**

The President of the Board

(João Almeida Lopes)