

Amendment to the Agreement between the Ministries of Finance, Economy and Health and the Pharmaceutical Industry

The Ministries of Finance, Economy and Health, and the Pharmaceutical Industry, through APIFARMA – Portuguese Association of the Pharmaceutical Industry, concluded, on March 15th 2016, the agreement for the triennium 2016-2018 (hereinafter referred to as the Agreement) which aims to implement certain measures in order to contribute to the sustainability of the National Health Service (NHS), to ensure access to medicines and to enhance the conditions of attractiveness for investment in Portugal.

In 2017 health policies will continue the ongoing processes aimed at improving equity in access, quality of healthcare and NHS efficiency given the challenges faced, namely the ageing of population and the growing burden of chronic diseases. In this context, it is essential to continue promoting a sustainable policy in the field of medicinal products in order to conciliate budgetary rigour with access to therapeutic innovation.

In 2016 several measures provided for under the agreement were implemented, namely the notified prices regime, the reinforcement of access to therapeutic innovation, through a substantial approval of innovative medicines, the publication of legislation containing the rules of the annual review of prices for 2017 and the reference countries Spain, France and Italy and with the introduction of a mechanism to reduce prices by no more than 10%.

Accordingly, for 2017 it is foreseen to maintain the promotion of a sustainable policy in the field of medicinal products namely through the revision of the mechanisms for dispensing and reimbursing medicinal products for outpatient chronic patients, the promotion of rationality in the use of public resources, allowing the introduction of innovation, and the encouragement of national research and production in the medicinal products sector.

For 2017 it is also important to continue to ensure the sustainability of the National Health Service (NHS), to guarantee access to medicinal products and to enhance the competitiveness of the industrial activities and the attractiveness for investment in Portugal.

These same goals derive from the National Strategy for Medicinal and Health Products, approved by the Council of Ministers Resolution no. 56/2016, and in line with the guidelines set out in the Major Planning Options for 2017, approved by Law No. 41/2016, of December 28th.

For this purpose, all the terms and conditions already assumed by the Portuguese State, represented by the Ministries of Finance, Economy and Health, and the Pharmaceutical Industry, represented by APIFARMA, are maintained in the Agreement concluded on March 15th, 2016, regarding the triennium 2016-2018.

Therefore, under the terms and for the purposes of the referred Agreement, it is important to properly update and adjust the agreed terms with express reference to the year 2017 and to establish the objectives and guidelines for the referred year, whereby the parties agree to conclude the following Amendment:

Clause 1

Subject

The purpose of this Amendment is to establish, under the Agreement concluded between the Ministries of Finance, Economy and Health and the Pharmaceutical Industry on March 15th 2016, for the year 2017, the terms of collaboration in the pursuit of the objectives provided for in clause 1 of the referred Agreement, the limits of the contribution of APIFARMA's associated companies and adherents to the Agreement as well as the respective deadlines for implementation for the year 2017.

Clause 2

Expenditure with medicinal products and Pharmaceutical Industry's financial contribution for the year 2017

1. The global financial contribution under the Agreement corresponds in 2017 to the minimum amount of 200 million euros, which will be quarterly updated according to the public expenditure with medicinal products of the NHS.
2. In the terms of clause 3, paragraph 2, of the Agreement, APIFARMA's associated companies and adherents of this Amendment has a minimum value of 150 million euros for the year 2017, being adjusted, in each quarter, according to the evolution of public expenditure with

medicinal products of the NHS and the respective market share, and as a result of the weighted percentage of the contributions resulting from the application of the contribution rates foreseen in Article 141 of Law No. 42 / 2016, of December 28th, and the percentages foreseen in clause 5, paragraph 1.

3. The annual clearance foreseen on paragraph 7 of clause 3 of the Agreement is performed based on the public expenditure values with medicinal products of the NHS on the year 2017 provided by INFARMED – the National Authority of Medicinal and Health Products, I.P. (INFARMED, I.P.), being applied to those values the rates foreseen in the Extraordinary Contribution Regime for the Pharmaceutical Industry in article 141 of Law no. 42/2016, of December 28th, up to the limit that would result from the application of the referred law to the total of the year 2017.
4. For the application of clause 6, paragraph 1, of the Agreement, regarding the payment of hospitals' debt, in the year 2017 the debt due in each period is compared to the debt due in the same period of the previous year, being reduced to the variation obtained, when applicable, the total value of the notes due under the Agreement and its Amendment, including those that are not issued yet.
5. The Monitoring Commission, foreseen in clause 12 of the Agreement, will quarterly analyse the evolution of the expenditure with medicinal products, of the contributions of the companies adherent to this Amendment and of the NHS expired debt to those companies, being responsible for proposing possible rebalancing measures in order to achieve the targets set out in the Agreement and in its Amendment.

Clause 3

Deadlines

1. The execution deadlines foreseen in the Agreement established for the year 2016 shall refer to the year 2017, on the following working day in the applicable cases.
2. Without prejudice to the previous paragraph, in the year 2017, the deadline foreseen in clause 5, paragraph 1, subparagraph a), of the Agreement should be changed to 31st of March 2017.

Clause 4

Measures to control public expenditure

1. Until the end of the first semester of 2017, and under the provisions of paragraph 2 of clause 8 of the Agreement, in the context of the publication of the notified prices, the signatory Ministries undertake to assess the results of the respective implementation, allowing to adjust the notified prices regime according to those results.
2. For the purposes of paragraph 4 of clause 8 of the Agreement it is established that the definition of a legal environment for the revision of the public reimbursement of medicinal products framework shall be initiated during the year 2017 in order to promote the respective adjustments.

Clause 5

Adhesion

The adhesion to this Amendment is carried out individually by the companies under the terms of clause 4 of the Agreement.

Clause 6

Transitional provision

The clauses of the Agreement shall remain in force, except for those matters that are inconsistent with the provisions of this Amendment.

Clause 7

Final provisions and coming into force

1. The Ministries of Economy and Health shall promote the necessary regulatory amendments in order to improve the structure and the competition of the market, particularly regarding the definition of the margins in the medicinal product chain and of the annual price revision procedures, in coordination with all the other parties involved.
2. The Ministries of Economy and Health undertake, due to the sustainability of the medicinal products chain, to analyse the conditions of the application of Directive 2011/62 /EU in the context of combating counterfeit medicinal products in order to reduce the impact of the inverse logistics.
3. This Amendment takes effect on January 1st 2017.

Lisbon, 3rd of February 2017