

Amendment to the Agreement between the Ministries of Health, the Economy and Employment and Finance and the Pharmaceutical Industry, of May 14 2012

Clause 1

Objecto

This Amendment is agreed in accordance with Clause 23 of the Agreement signed between the Ministries of Health, the Economy and Employment and Finance and the Pharmaceutical Industry, on May 14 2012, hereinafter referred to as Agreement.

Clause 2

Financial contribution for the year 2013

1. The pharmaceutical industry collaborates with a contribution in the amount of 122 million euros for the reduction of public expenditure on medicines in the hospital market, without prejudice to the global commitments assumed for the year 2013.
2. Pharmaceutical companies adhering to the Agreement and to this Amendment accept, in 2013, to work on reducing the expenditure referred in the preceding paragraph with a contribution whose value is proportional to the market share that they represent in 2013, calculated by reference to the total hospital market.
3. Companies not adhering to the Agreement and this Amendment will contribute to the effort of reducing medicines expenditure through the administrative measures deemed necessary by the Ministry of Health

Clause 3

Deadlines for regularization of the contribution of the Pharmaceutical Industry for the year 2013

1. The signatory parties to this Amendment undertake, under the 2013 market share terms, to pay 40% of the amount provided for in Clause 2, no. 2, in credit notes to the hospitals until the first half of October 2013. The contribution to be made results from the proportion of the turnover of each adherent company to the hospitals in the first semester.
2. The signatory parties to this Amendment undertake, under the 2013 market share terms, to pay 20% of the amount provided for in Clause 2, no. 2, in credit notes to the hospitals until the second half of October 2013. The contribution to be made results from the proportion of the turnover of each adherent company to the hospitals by August 30.

3. The signatory parties to this Amendment undertake, under the 2013 market share terms, to pay 20% of the amount provided for in Clause 2, no. 2, in credit notes to the hospitals until the first half of November 2013. The contribution to be made results from the proportion of the turnover of each adherent company to the hospitals by September 30.
4. The signatory parties to this Amendment undertake, under the 2013 market share terms, to pay 20% of the amount provided for in Clause 2, no. 2, in credit notes to the hospitals until November 30. The contribution to be made results from the proportion of the turnover of each adherent company to the hospitals by October 30.
5. The parties will share the necessary information to validate the final values of hospital expenditure, as well as information with adequate detail for the application of the respective contribution formulas, safeguarding confidentiality where applicable.
6. Pharmaceutical companies adhering to the Amendment, and members of APIFARMA, will only proceed to the issue of credit notes referred to in no. 3 and 4 of this Clause, after the Ministry of Health has settled the total hospital debts for hospital supplies prior to December 31, 2011, to the companies adhering to the Amendment until the end of October 2013.

Clause 4

Payment of hospital debts

1. The Ministry of Health undertakes to settle the total debt for hospital supplies prior to 31 December 2011 of the companies adhering to this Amendment until 30 October 2013.
2. The amount of hospital debt on December 31, 2013 should be less than the amount determined on December 31, 2012, fitting to the Ministry of Health every effort in order to begin the regularization of debts payment for the year 2012.

Clause 5

Marketing authorization of innovative medicines

The Ministry of Health is committed to promote the conditions for patients' access to medicines that are demonstrated to be innovative, namely by meeting the statutory deadlines for assessment and decision foreseen by the law.

Clause 6

Pricing scheme for not reimbursed prescription medicines

The Ministry of Health is committed to initiate the legislative process that allows not reimbursed prescription medicines to follow a notified price scheme, enabling a limited price variation, by a percentage to be set annually by INFARMED with the consultation of APIFARMA.

Clause 7

Legislative and administrative stability

The Ministry of Health will promote the maintenance of a stable legislative and regulatory framework for 2014, particularly in relation to the regulation of medicines prices, subject to changes and legislative and regulatory adjustments that are deemed necessary and appropriate to the sustainability of the NHS.

Clause 8

Coming into force

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