



## **COLLABORATION PROTOCOL BETWEEN THE MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY (MOH) AND FARMAINDUSTRIA (FI).**

Madrid, March 4th 2014

### **GATHERED**

On one part, Ms. Ana Mato Adrover, Minister of Health, Social Services and Equality, nominated by Royal Decree 1826/2011 December 21st (...).

On the other part, Ms. D.<sup>a</sup> Elvira Sanz Urgoiti, President of Farmaindustria (...).

### **EXPOSE**

**I.-** The right to have health protection is one of the most important social rights, taking into account its immediate link with the right to live, and its direct relation with quality living.

**II -** That the current economic environment makes the collaboration of all concerned agents indispensable, in order to contribute to guarantee the sustainability of the National Health System, with the overall goal of improving the citizen's health protection, taking into account the objectives of public deficit control, as well as boosting sectors' futures, such as the pharmaceutical industry.

**III -** That the necessary economic measures to guarantee the financial and economic stability and adequate healthcare expenditure to those of the European Union have called for the efforts on behalf of the Spanish pharmaceutical sector, which has contributed to the sustainability of the National Health System.

**IV -** That patient access to the best and most effective medicines is available, and that this access is granted in the shortest amount of time possible, and in conditions



of equality for the whole territory; this leads to a better quality of National Health Service, as well as a boost for industry resident in our country and, essentially, to an improvement in patients' care.

**V** - That the MoH, according to Spanish regulations, is the Department of Spanish General Administration in charge of the proposal and execution of Spanish Government's in the fields of health, healthcare planning and provisions and consumers, as well as for the exercise of the powers of the State's General Administration aimed at granting citizens the right to health protection.

**VI** - That the State holds the exclusive power to legislate pharmaceutical products, and the MOH has been granted the competences for the development and execution of pharmaceutical policy, as well as the functions regarding public financing and medicines and healthcare products price fixing.

**VII** - That Farmaindustria, according to its statutes, as far as the representation and defense of the collective and legitimate interests of their Members, has amongst its competences the faculty to promote, through the existing legal media, those legislative reforms, economic measures and, in general, the adoption of as many measures, as long as they can contribute to the progress of the pharmaceutical industrial sector.

**VIII** - That the MOH and Farmaindustria agree in the economic, health, and social importance of medicines and in the key role that pharmaceutical policy plays, both for the sustainability of the National Health system, as well as for the competitiveness of a sector of high added value for Spain, such as the pharmaceutical industry, based in innovation and international projection.

Taking all of the above points into account, and acknowledging both parties their respective powers and sufficient legal capacity to subscribe the Collaboration Protocol herein, they formalize it accepting that it will be governed by the following



## CLAUSES

### FIRST. THE AIM

The Protocol herein has an aim of establishing and articulating a space of collaboration between the MOH and Farmaindustria, to boost and develop the objectives which are of mutual interest for the parties.

### SECOND. FIELDS OF COLLABORATION

The fields in which this collaboration will be focused on are as follows:

- Examine the reference price system of medicines for human use which are included in the National Health System's pharmaceutical provision to respect the in-force intellectual property rights and to maintain their essential qualities, while achieving savings which are necessary for the System.
- Advance with regards to the functioning of centralized purchase procedures. This will allow the active participation of the industry, achieving important savings for the National Health System, while reinforcing the unity of Spanish pharmaceutical market.
- Follow up of the medicines' price and reimbursement model with the aim of accomplishing an efficient and fast access of patients to innovation, maximizing social welfare, and consolidating the sustainability of the National Health System.
- Analyse the monitoring and follow-up of the pharmaceutical expenditure evolution, public hospitals' debt, and access of patients to innovation through common indicators, taking European standards as a reference.



- Anchor the activity of the pharmaceutical industry in Spain with regards to production, exports and internationalization; qualified, diverse and equal employment; R&D with a special focus in this field both to basic research and to preclinical and clinical ones, taking advantage of the potential offered by public Spanish scientific and hospital infrastructure.

### **THIRD. COLLABORATION MEASURES**

Work collaboration, based on a mutual understanding, will be articulated through a Dialogue Platform which will hold monthly meetings. On the MOHs side, by the General Secretary for Healthcare for Consumers, and the General Director for the National Health System Basic Pharmacy and Services Portfolio. From Farmaindustria's side, by its President and General Director. Other experts or technicians of both parties will be able to participate in these meetings as well if both parties agree.

The Dialogue Platform will also be able to hold biannual meetings under the Presidency of the Minister of Health, Social Services and Equality, with the participation of Farmaindustria's Vice Presidents, summoned by the Minister of Minister of Health, Social Services and Equality.

### **FOURTH. ECONOMIC CONTRIBUTION OF BOTH PARTIES**

The signature of the Protocol herein does not entail economic commitments for either parties.

### **FIFTH. LENGTH AND RESOLUTION**

The Protocol herein will come into effect from the moment it is signed and its validity will be for a period of one year from that date. It will be tacitly extended for the same period, unless any of the parties expressly and in writing state the contrary, with a minimum anticipation of two months to the finalisation date.



Notwithstanding the above, the parties are enabled to call for the resolution of this Collaboration Protocol by a communication in written form, which should be formalised with a minimum anticipation of two months to the date of the desired finalization.

## **SIXTH. LEGAL FRAMEWORK AND CONFLICT RESOLUTION**

The Protocol herein has an administrative nature according to what is foreseen in Spanish current in-force legislation, although it remains outside of Public Sector Contracts, without prejudice that some of the principles contained in such text might be of application when resolving doubts or gaps which might arise in its interpretation or application.

The conflicts which might arise from its application and interpretation will be resolved within the Dialogue Platform itself, foreseen in clause three.

Both parties are in agreement to the content of this document, and with the aim of this agreement being documented; the Protocol herein is signed in the place and date indicated at the preamble.

MINISTER OF HEALTH

PRESIDENT OF FARMAINDUSTRIA

Ana Mato Adrover

Elvira Sanz Urgoiti