Farmaindustria requests a specific regulatory framework for biological medicines

A third of all international approved medicines already have a biological origin

Santander, September 4th 2014.- Farmaindustria's President, Elvira Sanz, requested a specific regulatory framework for biological medicines which would avoid legal disparity and establish grounds capable of attaining a balanced coexistence with the therapeutic, economic and industrial perspectives between original biological medicines and biosimilars.

Today, Elvira Sanz participated in the XIV Meeting of the Spanish Pharmaceutical Industry; this was held in the International University Menéndez Pelayo in Santander in collaboration with the Carlos III University of Madrid. The event was called "new biological medicines: therapeutic and economic revolution" and was officially opened by the Spanish Healthcare Secretary General, Pilar Farjas.

Currently, around a third of internationally approved medicines already have a biological foundation and account for almost 50% of pharmaceutical companies' pipelines. Seven out of 10 most sold medicines in the world today have a biological origin and it is estimated that more than 400 million patients are already enjoying the benefits from these treatments. Furthermore, it is estimated that in 2017 they will account for 20% of the whole of the worldwide pharmaceutical market.

During her speech, Sanz stated that biological medicines are currently providing solutions to diseases for which remedies have not been found by using chemical synthesis, while highlighting that the differences that exist between biological medicines and traditional medicines require a special treatment, from a legal point of view too.

For all of the above, she stressed that the most important challenge in this field is the definition of a specific regulatory framework which includes no substitution or interchange of biological medicines, and rejected the likening of biosimilars with generics, given that they respond to different logics. "Biologics and biosimilars are neither substitutable nor interchangeable. Small modifications on these complex structures might lead to very relevant changes in their efficacy and safety, thus doctors are the only ones able to make these key decisions where choosing treatments are concerned", she assured.

Although she is in favour of achieving savings -which arise from the loss of exclusivity of biological medicines- she insisted that the R&D based pharmaceutical industry cannot accept that said savings are brought about without considering basic principles such as non-interchangeable and no substitutions. "We defend -she stressed- maximum competition once the patent protection period has expired, but we do not accept practices which lead to a discrimination of original products".

Likewise, according Farmaindustria's President's opinion, a commitment on this kind of research is needed, making it possible for society to access the extraordinary opportunities which scientific advances offer in this field.

In this regard, she assured that in Spain, the R&D based pharmaceutical industry is prepared to face this challenge and lead in the development of therapies of biological origins, highlighting its differential contribution to fight disease and, therefore, making savings on social and healthcare resources for the country. As a matter of fact, she reminded us, that in Spain, the pharmaceutical industry invests around 200 €M annually (around 20% of its total R&D expenditure in the biotechnological field, and that around 60 new molecules of recombinant origin are currently in the development phases, with more than 275 ongoing clinical trials, mostly in the areas of oncology, immunology and hematology.

However, she also emphasized that in order to keep this challenge alive, the sector requires a stable and predictable framework which allows recovering the sustainable growth path at the same pace as the economy. "The pharmaceutical sector will give the economic and scientific efforts needed to maximize its potential in the field of development of new medicines, but its contribution to the healthcare of citizens and attaining the objectives of the healthcare systems should be expressly recognized. The economic analysis of these products cannot be based solely on their prices, but rather the value that they bring should be also taken into consideration", she concluded.