

## **The Andalusian Government is declaring some medicines as “equivalents”, without the appropriate scientific grounds or competences to do so**

**This was the opinion of Humberto Arnés, Director General of FARMAINDUSTRIA, during a conference held in Seville today**

**Sevilla, 1st July 2014.-** FARMAINDUSTRIA’s Director General, Humberto Arnés, gave a conference today about Equivalent Therapeutic Alternatives, in the framework of the event entitled “Therapeutic equivalents: a new hurdle for access to innovation?”, hosted today in Seville by the Joly Communication Group. This conference was organized with the aim of debating one of the main healthcare issues which has stirred a lot of interest recently in Andalusia: the call for a new framework agreement to homologize the selection of active ingredients for certain indications; this was announced by the Andalusian Health Service (SAS), and subsequently declared suspended as a precautionary measure last June 16th by the Andalusian Administrative Court of Contractual Appeals (TARC).

During his speech, FARMAINDUSTRIA’s Director General reminded us that even though two different active ingredients might share one indication, it does not imply that their pharmacological or therapeutic properties are the same. “What’s more –added Arnés– even when two different medicines share the same active ingredients, it is not in all cases that the FDA or EMA conclude there is a therapeutic equivalence”.

For therapeutic equivalences to exist, “besides the safety and efficacy of the medicines, other variables must be considered, such as its pharmacokinetics or subrogated effects”, continued FARMAINDUSTRIA’s Director General. This is the reason why he stressed that “only with therapeutic equivalences trials carried out, can it be concluded that two medicines have identical clinical effects or irrelevant differences”, which is something that will not happening under the framework agreement of therapeutic equivalents the SAS wants to introduce”.

Under the Spanish legal framework, potential declarations of therapeutic equivalence of two medicines correspond solely and exclusively to the Spanish Medicines Agency. Thus, for Arnés, in Andalusia “declarations of equivalence or similar efficacy are being issued by institutions who don’t have the powers or scientific backgrounds to do so”.

It needs to be stressed that this is the second time the SAS have announced a measure of these characteristics and both times, the Andalusian TARC has suspended them on precautionary grounds. In this second occasion, additionally, FARMAINDUSTRIA has lodged an administrative appeal against this framework agreement. The pharmaceutical industry is not the only sector opposing this measure, since diverse healthcare professional collectives, as well as scientific societies and patients’ associations have also openly expressed their rejection to this initiative.

Humberto Arnés also referred to the hazardous effects that the measure has on healthcare provision and public healthcare in general, taking into account that this framework agreement undermines the value of medicines, is a disincentive to research and harms the interests of pharmaceutical industry.

“It also provokes switching treatments without the doctor’s acknowledgement, as well as restricting the professionals’ prescription capacity”. Moreover, he indicated that patients are deprived of access to medicines which their doctors consider ideal, while citizens in other Spanish Autonomous Regions do have access to them.

“Ultimately –concluded the Director General of FARMAINDUSTRIA- medicines which have been authorized by the Spanish Minister of Health are being excluded from the public pharmaceutical supply, thus breaching equity in the National Health System”. The aim of this National Health System is actually to attain equitable access of Spanish patients to the best treatments and innovations, making it financially sustainable and compatible with a development of the business activity.

### Discussion

Following the conference of FARMAINDUSTRIA’s Director General, the event went on with a discussion where this same topic was dealt with and which was chaired by the President of the Advisory Healthcare Committee, Julio Sánchez Fierro, with the participation of Miguel Ángel Caracuel, from Spanish Society of Rheumatology; Antonio Aguado Núñez-Cornejo, Vice President of the Andalusian Council of Doctors and President of the Council of Doctors of Huelva; Rocío García Carbonero, from the Spanish Medical Oncology Society; Fernando Carballo, President of the Spanish Society of digestive pathology; M<sup>a</sup> Dolores Camero, President of Asanhemo; and José Miguel Fatás, Uría Menéndez’s Partner and ex-State Lawyer.

#### PARA MÁS INFORMACIÓN:

DEPARTAMENTO DE COMUNICACIÓN DE FARMAINDUSTRIA

Email: [blozano@farmaindustria.es](mailto:blozano@farmaindustria.es), [cfernandez@farmaindustria.es](mailto:cfernandez@farmaindustria.es)

Tel. 915 159 350

<http://farmaindustria.es/prensa>



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