ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

To
The honourable
Ms Eugenia Kanellopoulou
Vice President of EPY

Cc.: Mr Vassilios Kontozamanis, General Secretary of the Ministry of Health
Mr. Christos Giannaris, President of EPY
Mr Athanassion Argyriadis, Director of EPY

Chalandri, October 20, 2014

Re: Technical Specifications of the procurement process for medicinal products

Dear Ms Kanellopoulou,

We address this letter to you, further to the announcement dated 14.07.2014, re public consultation of Technical Specifications for the Unified International Tender of medicinal products. Based on the 26 Active substances of Medicinal Products posted at the website of E.K.A.P.T.Y. it was identified that a biologic agent has been included, and in particular, the active substance filgrastim.

We would like to point out that according to:

- The circular dated 26/11/2011 of the National Organization for Medicines entitled "Automatic Interchangeability of bio-similar medicinal products"
- The circular dated 13/03/2013 of the National Organization for Medicines entitled: "Explanatory circular on Bio-similars" and
- The circular dated 31/03/2014 of the Ministry of Health entitled "Circular on Bio-similars",

Bio-similar products are not generic medicinal products and the automatic substitution of biologic agents by bio-similars or the interchangeability between bio-similars is not recommended.

In addition, based on article 12 par. 2 of the Decision *oik.*3457/GG64/B/16.01.2014 biologic agents, either in terms of original products or of bio-similars, are not deemed directly interchangeable.

In support of the latter, comes EMP4, as specified in GG3057/18.11.2012, where it is stated that substitution of biotechnological products is not feasible or scientifically sound and this is why prescription based on the trade name is recommended.

Concluding, in the circular dated 31/03/2014 of the Ministry of Health, it is firmly stated that **it is prohibited** to include bio-similars in the P.P.Y.F.Y. for 2014. In cases, where a tender process concerning bio-similars has been scheduled, **it is cancelled**.

Taking into account the aforementioned, and for the prevention of any problems in the smooth operation of the tender, **we kindly request that you exclude the active substance *filgrastim* from the underlying tender and all biologic agents from any future procedures**.

Yours sincerely

Olympios Papadimitriou
Vice President of SFEE

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