ВСЕРОССИЙСКИЙ СОЮЗ ПАЦИЕНТОВ

125040, Moscow, Verhnyaya Str., 34, bld.1 tel./fax +7 (499) 426 06 42
http://www.patients.ru e-mail: pat@patients.ru

№ ВСП-01/018
19.03.13

TO:
D.A. Medvedev
Chairman of the Government of the Russian Federation

Dear Mister Dmitry Medvedev!

The patient community voices their concern and incomprehension as for the changes introduced by the Russian Health Ministry as the last amendments to Federal Law #61 “About pharmaceuticals turnover.”

We suspect that the last version of amendments meet the interests of the representatives of home and foreign pharmaceutical businesses who care for their proceeds volumes alone but not about the quality of pharmaceuticals they produce and far less about the wellbeing of patients having to use their product.

There is hardly another way to explain how Article 4 of p.12.3, which protects patients from the unscrupulous producer of a poor quality pharmaceutical and interpreted the term ‘interchangeable pharmaceutical as the pharmaceutical being not a biologic pharmaceutical with its therapeutic equivalence proved as related to the original pharmaceutical or, in its absence in the usage, to the comparison drug used in patients with the same indications and having equal quality and quantity composition in active substances as well as the dosage form, strength and route of administration’, has totally become anti-patient in its last edition: ‘interchangeable pharmaceutical is a pharmaceutical with its therapeutic equivalence proved as related to the original pharmaceutical or, in its absence in the usage, to the comparison drug used in patients with the same indications and having equal quality and quantity composition in active substances as well as the dosage form, strength and route of administration’, which makes biosimilar biological products interchangeable regardless of whatsoever provisos.

Biosimilar biological products produced in countries that lack the embedded international system to control the quality of a product, must not be allowed into the market at all without appropriate clinical trials, including comparative ones with the original drug. There is no such system in Russia yet.

It is known throughout the world that modern science does not approve of pharmaceutical substitution because even just a slight difference between the reference drug and its biosimilar biological product can be dangerous, that is why a medicinal substitution with the physician in charge not knowing puts a patient at risk.

Approximately half biosimilar biological products developed in the European Union (EU) and tested by the European Medicines Agency (EMA) have revealed unexpected clinical results in the course of their clinical assessment.

The professional association of biotechnologists (BIO) argues that ‘The contemporary science level is insufficient to identify the ability to interchange between multi-component advanced biological products‘, while the Food and Drug Administration (FDA) stated that ‘the way of possible identification of the ability to interchange between compound proteins has not been found to date.’

European experts believe that before a biosimilar biological product is given the status of an interchangeable one, it must undergo comparative clinical trials, while the registration certificate of a biosimilar biological product does not suggest having therapeutic equivalence of the drug to the reference one.

In accordance with the law about cut-price competition and innovations of biological pharmaceuticals, USA, 2009 (BPCI Act), with section 351 (k) of the law on the Public Health and Welfare (42 U.S.C. 262(k):

Biosimilar biological products shall be assessed through a comprehensive comparative analysis on each exponent in controlled preclinical and clinical alternate trials within an assigned time period to demonstrate the following:

- biosimilar biological products produce the same clinical result as the reference product in any given patient;
- alternating or switching between use of the original drug and use of a biosimilar biological product does not result in a greater risk as for immunogenicity, safety or diminished efficacy than continuation of use of the original drug.

Medical experts worldwide believe that biosimilar biological products cannot be considered medicinal counterparts for original/licensed pharmaceuticals and, therefore, cannot be used to substitute them and must not be equally prescribed.

Neither nation within the EU supports the interchangeability.

So, why in our country, where there is much talking about positive amendments for the wellbeing of citizens, do we still have to choose between the rate of development of the pharmaceutical industry and people’s life? Why must millions of our citizens pay by their health and lives for the comfort of dishonest moneymakers?

We are calling upon you to support the original amendment by the Russian Health Ministry in Article 4 of p.12.3, Federal Law-61 “About pharmaceuticals turnover”, which protects patients from the unscrupulous producer of a poor quality pharmaceutical – ‘interchangeable pharmaceutical is a pharmaceutical being not a biologic pharmaceutical with its therapeutic equivalence proved as related to the original pharmaceutical or, in its absence in the usage, to the comparison drug used in patients with the same indications and having equal quality and quantity composition in active substances as well as the dosage form, strength and route of administration.’

Yours respectfully,

Co-Chairs of the All-Russian Patients Union

Yu. A. Zhulev

Yan V. Vlasov

Ответственный исполнитель _____