US Food and Drug Administration Issues New Biosimilars Action Plan

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The US Food and Drug Administration issued a new Biosimilars Action Plan in July 2018 ("**Plan"**). The Plan's main goals are to promote innovation, access to medicine, competition, introduce key actions (including establishing a new Office of Therapeutic Biologics and Biosimilars), as well as develop and implement new review tools.

In 2013, 22% of the US $754 billion global pharmaceuticals market consisted of biologics. This percentage is expected to be 30% in 2020. In 2014, seven of the top ten most sold pharmaceuticals in the world was biologics. In 2020, patents are expected to expire for biologics worth US $80 billion (source).

The high values involved mean pharmaceutical companies and government regulators alike are very interested in biotechnological pharmaceuticals.

The Turkish Biotechnology Strategy and Action Plan was prepared in 2015. Since then, several steps have been taken, such as assembling the Biotechnology Working Group, plus supporting companies active in R&D activities and technology transfer.

The Scientific and Technological Research Council of Turkey supports several projects regarding biosimilars, with each project's budget worth more than 20 million Turkish Liras.

Please see this link for the full text of the Plan (only available in English).

Related Attorneys

- GÖKÇE ?ZG?, LL.M.
- MERVE ALTINAY ÖZTEK?N