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"In The Name" of biosimilars: Trademarks issues

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The European Medicines Agency in its "Guideline on the acceptability of names for human medicinal products processed through the centralised procedure" detected the criteria to define the name of medicines. They are applicable also to biosimilars. The invented name of medicinal products represents an important part of the community marketing authorisation. The name of a medicine may be composed by an invented name, different from the common name, or a common (i.e. the international non-proprietary name (INN)) or scientific name linked with the trade mark or the name of the marketing authorisation holder (art. 1(20) of Directive 2001/83/EC). EMA plays an important role, through its Name Review Group (NRG), in checking of the name within the authorisation procedure. During the last decades, it is being noticed more all the time the need to identify biological medicinal products and biosimilars with a specific code. A meeting which took place in Geneva on April 2015 organized by WHO shed a light on this issue and led to the proposal of a four-letter code suffix (the Biological Qualifier) assigned randomly and generated by an automatic system that should accompany the INN. FDA issued in 2017 the final version of the guide "Nonproprietary Naming of Biological Products", in which FDA set out specific criteria to define the name of biosimilars. In particular, biosimilar products would share the core name with the biological originators, while a four-letter code suffix will distinguish them. It is interesting, firstly, to analyse the difference between the European and the US approach about the issue of the naming of biosimilars and, secondly, to gather the last updates about this matter.

Biography

Roberto Valenti is a partner at DLA Piper Italy. He focuses on IP litigation, including matters relating to trademarks, copyrights, designs, unfair competition and misleading and comparative advertising. He also has experience dealing with IP non-contentious matters, such as drafting licence and transfer agreements relating to trademarks, copyrights and designs, with a special focus in the life science sector. Roberto is also engaged in verifying IP portfolios and evaluating intangible assets in M&A scenarios. He has completed PhD in Intellectual Property from the University of Pavia. In the last 7 years he has been the Chairman of the Life Science Working Group of the American Chamber of Commerce in Italy. He is commended in the WTR 1000: The World's Leading Trademark Professionals 2017. Chambers Europe, Chambers Global, The Legal 500 EMEA and a number of client surveys have identified him as a leading individual in the IP field, with particular reference to the Life Science arena. He is listed as Acritas Star™ Lawyer 2017. He also worked for a leading Italian IP law firm.

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