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The Pharmaceutical Industry - Italy

The pharmaceutical industry has been in the news relatively frequently recently with several cases having been in the public eye. These include the 'pioneering' case regarding Bayer, the pharmaceutical company and its use of Twitter, and the recent decision from Facebook to remove a policy exempting all pharmaceutical company pages from open "walls". Taking a look at this industry and the legal issues currently surrounding it in Italy, *Lawyer Monthly* spoke to Francesco Setti, partner at Italian law firm, *Avvocati Associati Franzosi Dal Negro Pensato Setti*.

Q The pharmaceutical company, Bayer, was recently said to have brought 'discredit' on the industry through its use of Twitter to promote the launch of its medicines, Levitra and Sativex. The Prescription Medicines Code of Practice Authority ruled that neither tweets had been approved by qualified employees to ensure they met regulatory requirements, and, according to reports, it is the first breach of the ABPI Code of Practice. What are your opinions on this?

The use of digital media in the advertisement of medicinal products triggers some challenging issues within, at least as far as Italy is concerned, basically de-regulated legal and regulatory framework. Internet and new media in general, as a promotional tool, have been addressed only recently by the Italian Regulatory Authorities by guidelines issued on February 2010 – however concerning only OTC drugs, medical devices and veterinary products - but the regulation is still at a very initial stage, leaving some pending issues open to interpretation (i.e. how these rules apply to prescription drugs or the use of social networks not only for promotion of medicines but also in relation to clinical trials for example as an information tool about the existence of the trial).

However, under the current regulation, in Italy, Bayer's practice would have been ruled non compliant as well. Besides the obvious fact that

these were prescription only medicines, therefore per se banned from any form of advertisement, the Italian Regulatory Authority is of the view that any message shall be considered as a separated advertisement which needs to be specifically and individually approved by the regulatory authority, regardless of the fact that the content of the message itself might have been already approved for use in a different format or context (for example banners, overlapping frames; pop-up; links to a third party's website).

Q What are the main types of cases you deal with within the pharmaceutical sector? Is it mainly IP-related?

Our firm deals with a wide array of IP, regulatory and administrative matters surrounding pharmaceuticals and medical devices. We assist our clients in all legal and regulatory matters related to authorisation, licensing, marketing, and distribution of medicinal products as well as medical devices and government regulation of clinical trials and research studies.

Q What are the most common types of litigation to arise?

Litigations are mainly either IP-related - recently concerning in particular originators vs. genericists or connected to parallel importations – but we face

also frequent cases connected with administrative matters such as reimbursement, freedom of information and public procurements .

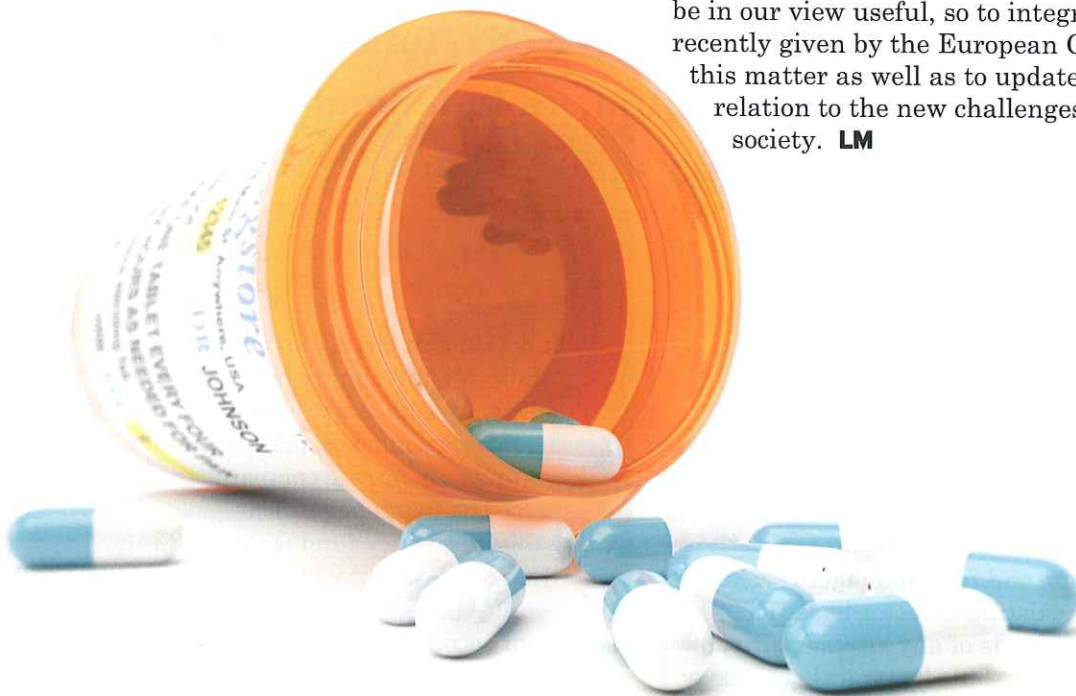
Q What are the key legal challenges that arise specifically within the pharma industry?

Recently, issues related to generics and bio-similar products are becoming more and more pressing, not only under the obvious IP side but also in connection with the reimbursement by the NHS (whether products can be considered actually substitutable as to their safety and effectiveness) and public procurements (disputes among competitors whether biological products can be considered equivalent).

cuts in recent years with a purpose of cost-containment for the NHS. Moreover it is worth mentioning a new law issued on July 2011 (D.L. 70/2011) which has significantly modified the public procurement system in Italy, through amendments of the Italian Code on publicly procured contracts. In particular, a newly introduced provision now establishes that, in principle, bidders in public tenders can only be excluded by the contracting authority in limited and specific cases provided by the law rather than by the contracting authority itself. Such a provision is expected to plummet the litigation rate related to public procurements.

Q Do you see the need for any legislative changes? What are they and why?

A more systematic regulation on advertisement of medicinal products and scientific information would be in our view useful, so to integrate the inputs recently given by the European Court of Justice on this matter as well as to update legislation in relation to the new challenges of the digital society. **LM**



Q How do you overcome/navigate these challenges?

Legal and business matters are getting more and more linked to each other, therefore in our practice, we try to focus on practical, business oriented solutions, acknowledging also the need of the clients to get fast and timely answers to their requests.

Q Have there been any legislative changes to affect your work in this sector recently?

The mainly domestic legislative changes concerns pricing and reimbursement of generics and off-patent drugs which have undergone several price

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