A spoonful of medicine

Over the last 12months, deal activity across the board has slowed, however the pharmaceutical sector has fared well in comparison to others. ACQ talks to the experts...

Leonor Pimenta Pissarra

Paulo Pinheiro

Portugal

Paulo Pinheiro is the partner heading the Public and Health areas of practice of the law firm Vieira de Almeida & Associados ("VdA").

Leonor Pimenta Pissarra is currently a managing associate in the Health area of practice of VdA.

VdA is a major, independent Portuguese firm, with a headcount of 150 lawyers. The firm's Health practice is traditionally one of the areas of high level of expertise and as a result of the high degree of specialisation, accumulated over the years, VdA has a strong reputation amongst the companies and the regulatory authorities of the health sector, and represents, on a regular and continuous basis, most of the relevant research and development pharmaceutical companies operating in Portugal.

VdA's assistance to the pharmaceutical companies covers all legal and regulatory matters, such as (i) negotiations with the competent health authorities in the context of reimbursement of medicines, (ii) marketing authorisations and renewals, (iii) prices, (iv) manufacture, (v) wholesale distribution, (vi) competition, (vii) clinical trials (viii) public procurement and contract negotiations with public and private agents.

"Recently, several pharma companies have developed and implemented compliance programmes where policies, regulations and procedures, aimed at ensuring the consistency of the advertising activities with the respective applicable legal framework, have been approved. VdA has been very active in providing assistance to pharma companies in drafting, reviewing and guaranteeing that such policies, regulations and procedures comply with the Portuguese legal framework by reviewing standard operating procedures ("SOPs") and other global and specific policies and procedures.

"Matters related to promotional and advertising activities have also played a central role within the assistance provided by the Firm as various issues concerning this area of practice are raised almost on a daily basis, and within which the members of the Health group have developed relevant skills.

"In Portugal, the advertising of medicinal products is subject to somewhat dispersed regulation. However, its main applicable regime is set-forth in a single decree, usually referred to as the "Medicines Code", which is established in Decree-Law 176/2006, 30th August 2006, ("Medicines Code"), transposing Directive 2001/83/EC, of 6th November 2001, on the Community Code relating to medicinal products for human use.

"In Portugal, the authority responsible for the regulation and supervision of the advertising of medicinal products is INFARMED (the Portuguese Health Regulatory Authority).

"Lastly, a matter that will most certainly raise challenges in the future in what promotion of medicines is concerned is the distinction between information and advertising, specially in direct-to-consumer activities."

England

Dr Rosanna Cooper is Global Head of RT Coopers. She is in charge of pharmaceutical and the regulatory department acting on behalf of pharmaceutical and biotech companies.

"Dr Cooper is an expert in pharmaceutical law and combines specialist scientific knowledge and understanding of the pharmaceutical and biopharmaceutical sectors, with the requisite legal experience to provide specialist advice in the areas of advertising and promotions, advertising and selling on the Internet, evaluation, protection and exploitation of intellectual property rights, marketing authorisations, freedom to operate searches, Regulatory compliance with UK and European Union to companies globally that may be launching new pharmaceutical products in the UK and/or licensing, importing or exporting pharmaceutical products.

RT Coopers' clients are global and vary from small to medium sized enterprises to large corporate organisations all doing business in the pharmaceutical sector in the UK.

"Under the expertise of Dr Rosanna Cooper, the firm has been advising and assisting pharmaceutical, biopharmaceutical and biotech companies since early 2002, with obtaining marketing authorisations, informed consents, advising on virtual trading in pharmaceutical products, advertising on the Internet and more recently advertising and data protection issues."

"To advertise a pharmaceutical product or medicine in the UK, the medicine must have a valid marketing authorisation and there are national and European legislations that have to be adhered to regarding the contents of advertisements and promotions in relation to the prescription, supply, sale or consumption of medicinal products encompassing written or spoken words intended to encourage prescription or supply by health professionals and use of medicines by the general public."

"The two main legislation are the Medicines (Advertising) Regulations 1994 (SI 1994/1932); the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933), both as amended ("Regulations")."

"The Regulations govern advertisements by prescribers or suppliers of medicines, or the purchase of over-the-counter medicines by the public. In addition to the Regulations there are Codes of Conduct that a company will have to comply with. The advertising of prescription-only medicines is governed by the Association of the British Pharmaceutical Industry (ABPI) Code of Practice ("Code"), which is regulated by the Prescription Medicines Code of Practice Authority ("PMCPA")."

"The advertising of over-the-counter medicines to the general public is governed by the Proprietary Association of Great Britain ("PAGB") Consumer Code and the advertising of over-the-counter medicines to qualified persons prescribing or supplying medicines is governed by the PAGB Professional Code."

"The Code relates to the supply of samples, and the requirement for all promotional material to include a prominent statement regarding reporting of adverse events.

"The Medicines and Healthcare products Regulatory Agency ("MHRA") are responsible for enforcing these Regulations. The MHRA works with other statutory regulators and self-regulatory bodies to ensure advertising is fully compliant with EC and UK medicines law. These include, Advertising Standards Authority (general advertising), Proprietary Association of Great Britain (over the counter medicines), Prescription Medicines Code of Practice Authority (prescription medicines).

"The Blue Guide, Advertising and Promotion of Medicines in the UK (2005), issued by the MHRA, includes guidance on the relevant UK law for advertising to health professionals. The MHRA ensures that medicine advertising is fully compliant with UK medicines law.

"The Regulations allow the MHRA to require sight of advertising before they are issued.

"All advertising must reflect the approved indication accurately in its entirety. Wording that implies efficacy has been established is unlikely to be acceptable and the results of any clinical studies must not be presented in a way that misrepresents the weight to be attached to such data.

"The PAGB, British Herbal Medicines Association and Health Food Manufacturer's Association require submission of advertising material in certain circumstances for pre-vetting before they are issued.

"The Regulations prohibit advertising of prescription only medicines to the public. The Regulations prohibit advertisements directed exclusively or principally at children (under-16s).

Consumers must not be misled with regards to the benefits of the medicine in comparison to other products in the category. The Business Protection from Misleading Marketing Regulations 2008; and The Consumer Protection from Unfair Trading Regulations 2008 also govern advertising of medicines.

In the UK, the promotion of prescription only medicines to the public on the Internet is prohibited.

"At the moment, we are seeing a number of European companies coming to the UK to do business such as virtual trading in pharmaceutical products. For the time being if those companies are based in the UK and exporting medicines outside the European Union they are less restrictions.

"The self regulation of pharmaceutical advertising is going to tighten as more pharmaceutical companies enter the UK market."

China

Chiang Ling Li and Haifeng Huang is a partner at Jones Day Hong Kong

Jones Day is an international law firm with 32 locations in centres of business and finance throughout the world. With more than 2,400 lawyers, including over 400 in Europe, and 200 in Asia, it ranks among the world's largest law firms. The Firm has one of the largest China practices of any full service law firm, with four offices and over 150 lawyers in Greater China. Jones Day acts as principal outside counsel to, or provides significant legal representation for, more than half of the Fortune Global 500 companies.

Jones Day's pharmaceutical team advises participants in the pharmaceutical industry worldwide. The Firm's clients include multinational pharmaceutical companies, domestic pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, and medical device companies. The lawyers of the pharmaceutical team bring together numerous legal disciplines to provide specialized services to clients. Those services cover the full-range of issues confronting participants in the pharmaceutical industry such as litigation, intellectual property, financing and M&A.

"A vast body of laws and regulations govern the advertisement of pharmaceutical products in the PRC. The main pieces of relevant legislation t Advertising Law of the People's Republic of China, the Regulations on Administration of Advertisements, the Detailed Implementing Rules for the Regulation on Advertising and the Measures for the Administration of Advertising on Printed Matters which are applicable to print advertisements.

Additionally, laws and regulation which apply specifically to the advertisement of pharmaceutical products such as Laws of the People's Republic of China for the Administration of Pharmaceuticals and Standards for the Examination and Publication of Drug Advertisements (¡§Drug Advertisement Standards¡¨) have also been adopted .

°The PRC is expected to become the fifth largest pharmaceutical market in the world by 2010. Many pharmaceutical enterprises consider China as a large market and hence will invest much more money in pharmaceutical advertising.

Despite the enactment of significant regulatory restrictions on pharmaceutical advertising, illegal advertising remains a major issue. In recent years, the FDA has announced a series of measures designed to improve advertising standards, including prohibiting advertisement of certain classes of prescription drugs and issuing standards for labelling. Also, local governmental departments have adopted various measures to reinforce the monitoring and supervision of pharmaceutical advertising such as issuing blacklists of offending companies and launching online supervision systems.

However, the relevant laws and rules governing pharmaceutical advertising still need improvement. Recently, the FDA's Deputy Commissioner and other professionals in this field have urged the government to reinforce the monitoring and supervision of pharmaceutical advertisements, especially those published on the Internet. Therefore, it may be expected that the existing laws and rules governing pharmaceutical advertising will be implemented more strictly, and some new rules governing pharmaceutical advertising on the Internet may be adopted in the near future. **ACQ**

DETAILS

RT Coopers
Telfords Yard
6/8 The Highway
London
E1W 2BS
+44 (0) 207 488 9947
enquiries@rtcoopers
solicitors.com
www.rtcoopers.com

Vieira de Almeida &
Associados, Sociedade de
Advogados, RL
Av. Duarte Pacheco 26
1070-110 Lisboa
Portugal
+351 21 311 3400
Lisboa@vda.pt
www.vda.pt
Paulo Pinheiro – pp@vda.pt
Leonor Pimenta
Pissarra – lpp@vda.pt

Chiang Ling Li
Jones Day
29th Floor, Edinburgh Tower
The Landmark
15 Queen's Road Central
Hong Kong
+3189 7338
+2868 5871
chiang ling li@JonesDay.com
www.JonesDay.com

Haifeng Huang
Jones Day
29th Floor, Edinburgh Tower
The Landmark
15 Queen's Road Central
Hong Kong
+3189 7253
+2868 5871
hfhuang@jonesday.com
www.JonesDay.com