The International Comparative Legal Guide to:

Pharmaceutical Advertising 2008

A practical insight to cross-border Pharmaceutical Advertising work

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Advokatfirmaet Haavind Vislie AS
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Chapter 14

Croatia

1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in Croatia?

Advertising of medicinal products is governed by the Law on Medicinal Products (Official Gazette No. 71/07: the Law) adopted on 21 July 2007. The second source of law is By-law on Method of Advertising and Rendering Information on Medicinal and Homeopathic Products and Medicinal Devices (Official Gazette No. 62/05; further: the By-law) last amended on 12 May 2005 by the Croatian Ministry of Health (further: MoH) in execution of its duty of implementation of general rules set by the Law. Given the fact that the Law provides that all by-laws passed on the basis of the former Law (that of 2003) should be amended in order to reflect the provisions of the new Law (that of 2007), it is expected that the new By-law shall be issued in a time to come.

In addition to the rules specific for advertising in pharmaceutical sector (lex specialis), the other general legislation which might be relevant is: Law on Protection of Consumers (Official Gazette No. 79/07), Law on Trade - provisions on unfair market competition (Official Gazette No. 49/03, 170/03, 55/04) and, to the lesser extent, Media Law (Official Gazette No. 59/04).

Finally, members of R&D oriented industry present on the Croatian market agreed to comply, as members of Croatian Association of Research-Based Pharmaceutical Companies (further referred to as: CARPC) - an association with liaison status of EFPIA, with the Code of Conduct on Advertising of Medicinal Products (further referred to as: the Code) which takes into account - in addition to national legislation - Code of Pharmaceutical Marketing Practices of IFPMA and the European Code of Practice for the Promotion of Medicines of EFPIA. As the conduct requirements of the Code are binding only to member companies of CARPC (and sanctioned by CARPC) this report shall focus on the current status of statutory legislation in Croatia.

1.2 How is “advertising” defined?

The Law defines advertising as “each form of rendering information on medicinal products with the purpose of promoting prescription, issuance, sales and consumption in written, visual, audio, verbal, electronic, digital or any other form”.

Under the Law, advertising must be objective, with the purpose of enhancing rational pharmacotherapy and must not be misleading, whereas By-law demands that such advertising must provide true and scientifically proved information on medicinal product, observing ethical criteria, all with the purpose of proper and rational use, and must not be misleading.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as “sign off” of promotional copy requirements?

Companies must ensure that they comply with the applicable laws and regulations and codes to which they are subject. By-law merely imposes general obligations to the companies and, namely:

- to organise a division i.e. appoint a person who shall be responsible for rendering information on medicinal products marketed by the respective company;
- to ensure that advertising-related decisions of MoH shall be immediately enforced;
- to proceed in line with any requests of MoH issued in the process of supervision;
- to provide MoH with all information required for conduct of supervision;
- to ensure that employees engaged in advertising of medicinal products to healthcare professionals must be properly trained and suitably qualified (a high degree in medicinal sciences is sought); and
- to retain all promotional materials (irrespective to their media) and keep records on the date and the place of their publication/dissemination, the persons to whom such materials were delivered and professional meetings and lectures sponsored by the respective companies.

There is no specific requirement contained in any of the abovementioned sources of law that provide for the specific methods of carrying out of the particular activities e.g. certification of promotional materials prior to their issuance. In practice, companies develop various compliance plans i.e. standards and policies to guide their business conduct in the area of advertising.

1.4 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Advertising must not be approved before use by a regulatory or industry authority.

However, By-law provides that companies must preserve and provide at the request of the Minister of Health copies of all advertising (materials), with indication of the users to whom such materials were addressed, method of publishing and the date of the
first publication. In other words, MoH could invite companies to submit information on advertising for their inspection.

1.5 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Where the competent authority rules that there is breach of the Law and the By-law, it does have a power to stop breaching activity. Corrective statements, as such, are not provided in any of the abovementioned sources of law. The Law qualifies non-compliant advertising as an act of misdemeanour for which a company may be fined. If a pharmaceutical inspector of MoH establishes that non-compliance may be qualified either as criminal offence or an act of misdemeanour, it must without delay, and within 15 days from the date of completion of the inspection at its latest, submit an appropriate request to a competent authority.

Decisions of MoH inspectors cannot be appealed in a regular administrative proceedings - they can be contested only in a proceedings before Administrative Court of Croatia, by filing of an administrative suit. On the other hand, if subject to criminal or misdemeanour proceedings, companies are entitled to use all remedies provided in procedural rules applied in such cases.

1.6 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

Dealing with non-compliance and sanctioning may be entrusted to various enforcement authorities. First of all, under the Law, MoH officials - inspectors in exercising of their supervision powers - may issue a number of orders targeted at immediate stop of infringing activities and remedying of a non-compliant situations. The Law qualifies breaches of the advertising rules as an act of misdemeanour which is sanctioned with fines ranging between approx. 13,500.00 - 20,000.00 EUR for a company and 1,300.00 - 2,000.00 EUR for an authorised person of the company. Such offences are dealt with the Misdemeanour Courts - at the initiative of the inspectors of MoH, but could be initiated also by competitors and other interested groups/individuals.

Particularly high fines in the misdemeanour proceedings are envisaged for persons who contravene the provision on prohibition of advertising of prescription medicines and medicinal treatments under the Media Law: such persons may be faced with fines of up to approx. 135,000 EUR (legal persons) and 13,000 EUR (authorised representatives of the companies).

Competitors may take direct actions through civil courts on the grounds of unfair competition, but as there is no straightforward provision in the Law on Trade (Official Gazette No. 49/03, 55/04) which would provide a ready basis for such complaint, it depends on the circumstances of the individual case if the alleged behaviour would qualify as an act of unfair competition and be punished accordingly (through compensation of damages or other manner of compensation).

In addition to that, any person with legitimate interest as well as the State Inspectorate in performance of its duties are entitled, under the Law on Protection of Consumers, to address the civil court with the request of immediate stop of published, but also unpublished, advertisements which are deceiving or which qualify as prohibited comparative advertisements. The State Inspectorate has an authority itself to impose an immediate order to stop unlawful advertising effective until the court resolves the matter: the decision of the State Inspectorate does not delay the enforcement of such order.

Matters of advertising non-compliance in Croatia are rather rare and, even if civil and criminal remedies might be or are invoked against the companies (usually, as a result of newspaper reports on the subject or forms of disguised advertising that caught the attention of prosecuting authorities), their outcomes are not at all or are rarely published. This, of course, does not mean that there are no such cases or that no enforcement actions exist.

1.7 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do the authorities investigate matters brought to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self- regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

For the time being, no such relationship is formally established. However, it may be fairly assumed that - since self-regulatory acts are usually taken into consideration country - specific laws - that the evidence on self-imposed compliance practices puts the company in a stronger position to address the questions of the enforcement authorities.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

The Law expressly prohibits advertising of medicinal products which do not have marketing authorisation, except on professional and scientific meetings and in professional literature providing that:

a) the marketing authorisation process for a particular product had been initiated; and

b) only the generic name is used, with no indication of the manufacturer.
However, mentioned limitations do not apply to international professional conferences taking place in Croatia.

Under the Law, informative publications on the results of clinical trials qualifies as rendering information on medicinal products which is permitted activity. As the MoH did not, at the time of this report, pass the By-law providing for more specific rules on the manner in which such information may be disseminated, we are not able to report more extensively on the issue.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Pursuant to the Law, information of unauthorised medicines may be published but only subject to the following rules: a) the information may appear only in the professional literature; b) the proceedings for issuance of marketing authorisation for such product must be pending; and c) only the generic name of the product can be used, without disclosure of the identity of its manufacturer. Of course, such information must always be compliant with other general requirements for lawful advertising such as demand for objectiveness, for enhancing of rational pharmacotherapy and never misleading (pursuant to the Law) and be true and scientifically proved, observing ethical criteria, with the goal of proper use of such product (pursuant to the By-law).

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

As issuance of press release implies rendering information to general audiences, such information on unlicensed medicinal product is prohibited. Croatian By-law explicitly forbids rendering information on unleashed medicinal products in any form (apart from circumstances described in the question 2.1 above): there are no exemptions for press releases.

However, given the latest legislative developments in Croatia with a view to allow rendering information on medicinal products - including informative reports on clinical trials as well as any impartial and objective informing of the public on diseases, their prevention and available treatment methods - perhaps press releases that would be drafted for non-promotional purposes (e.g. to give information important for understanding of the financial position of the company) and that would make no claims and statements as to the effectiveness of the (un)authorised medicine/indication, that would use generic name of the substance and whose tone and the general attitude would not be promotional would be allowed.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

There are no specific rules on unsolicited information given to health professionals. As mentioned above, general rule on prohibition of rendering of any information on unauthorised products/indications (exceptions are provided in limited situations, as explained above, under question 2.1) is not only aimed at the protection of consumers (general public), but is also directed against any form of influencing health professionals in their decisions prior to marketing authorisation and the actual launch of the product.

Following from the requirement that company’s employees should give during their visits to health professionals a written document - complete summary of characteristics as well as indications consistent with the terms of authorisation - it could be deduced that no such information can be given for a product/indication which is not authorised in Croatia.

The practice, however, shows that many companies in Croatia - if engaged in such activity - opt for the responsible approach by insisting on written requests of the health professional, internal checking of the information against risks of charges for unlawful promotion and with regard to other rules of their respective compliance plans.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

No specific rules, other than general prohibition of advertising of unauthorised products, address this issue.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

No specific rules, other than general prohibition of advertising of unauthorised products, address this issue.

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

Advertisements directed to health professionals must contain the following information:
- prescribing information;
- full summary of product characteristics and the approved indication whose type size is no less than 3 mm and should be otherwise presented in a manner which assists its readability and comprehension;
- the date when the material was drawn up or last revised;
- in case of quoting literature, the source of quotation; and
- finally, all such advertisements must enable the recipient to create her/his own opinion on the therapeutic value of the product.

3.2 Is it a requirement that there be data from any or a particular number of “head to head” clinical trials before comparative claims are made?

No specific advertising rules address this issue.

3.3 What rules govern comparator advertisements? Is it possible to use another company’s brand name as part of that comparison? Would it be possible to refer to a competitor’s product which had not yet been authorised in Croatia?

By-law specifically prohibits distortion of the therapeutic value of the other product or raising doubts with regard to the value of the other product. It also prohibits statements targeted at convincing health professionals that one product should be replaced with the other from the same therapeutical class without existence of clear medical indication. No other rules that could be, directly or
indirectly, interpreted as rules on comparator advertising are contained in the sources of law stated under question 1.1 above.

However, another law: Law on Protection of Consumers provides for criteria of lawful comparative advertising in general which may be applicable also to medicinal products. Under quoted Law, comparator advertising is any advertising which, for the purpose of promotion of a certain product, directly or indirectly refers to the competitor i.e. competitor’s product. Comparator advertising shall be admissible if:

- it is not misleading (or potentially misleading for its recipients thus probably affecting their economic behaviour);
- if compared products are intended for satisfaction of the same needs or if they are intended for the same purpose;
- if the characteristics of concerned products - which are material, essential, comparable and verifiable - are compared objectively;
- if such advertising does not create confusion on the market on the part of the advertisers and their competitors i.e. does not create confusion on the market with respect to the concerned product and the competitive products;
- if such advertising is not degrading for competitor, its activities, products services, trademarks or brands;
- if the object of comparison, in case of products with the indication of origin, are products of the same origin;
- if such advertising is not intended to unfair exploitation of the goodwill of trademark, brand or other characteristics of the competitor, its product or service; or
- if such advertising does not address product or service which are declared as copies of original brands of products/services.

Provided that the above criteria are observed, it would be possible to use other company’s brand name as the part of comparison providing, however, that no unfair advantage is taken.

Yet another law: Law on Trade which deals with the acts of unfair competition, must also be observed in consideration of admissibility of comparator advertisements and use of other company’s brands. Among others, Law on Trade expressly determines that the following behaviour qualifies as the act of unfair competition:

- advertising of goods/services stating or using expressions targeted at (unfair) exploitation of reputation of another entrepreneur; its products/services i.e. products/services of another entrepreneur; and/or
- unjustified use of the name, company name, brand or other mark of the another entrepreneur.

In other words, comparator advertisements would be permitted provided that they are fair and balanced in terms of both, Law on Protection of Consumers and the Law on Trade.

3.4 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

No specific rules are governing distribution of scientific materials to health professionals.

3.5 Are “teaser” advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

“Teaser” advertisements are not referred to in the concerned sources of law. The lawfulness of such communication would largely depend on the circumstances of each particular case and a set of rules (on advertising, unfair competition etc.) to which this type of behaviour may be subject.

4 Gifts and Financial Incentives

4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

Free samples of the medicinal product can be provided to a health professional under the following conditions:

- a free sample may be given at the written request of the health professional, only once and in the maximum quantity of 2 (two) smallest original packages of the product;
- only smallest authorised packages of the product can be given as free samples and those should be identical to the usual packages available on the market;
- packages must bear clearly visible label indicating “free sample”;
- each sample must be accompanied by summary of product characteristics and approved indication for use;
- health professional must sign certificate of receipt of the sample and the company must maintain a system of recording of sampling with personal data of the concerned health professional, name of the health institution or private practice and the date of delivery of sample; and
- it is not allowed to provide samples that contain opiates.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

By-law explicitly prohibits giving gifts (monetary awards or any other gains, or promising such benefits) to health professionals as an inducement for prescribing, supplying, recommending or purchasing of medicinal products. By-law also prohibits health professionals from receiving or actively seeking such benefits.

The issue of giving gifts to medical practitioners is, therefore, a highly sensitive issue which calls for careful consideration of the circumstances on the case-to-case basis with a view to restrictions and requirements set by a number of other applicable laws. A complete and comprehensive review of each and every aspect of laws which should be taken into consideration would exceed the purpose of this general overview, therefore information rendered hereunder is understandably limited to the most important aspects. In principle, there are no obstacles to give donations (in kind or money) to private practitioners providing that giving or promising of gifts, financial and other benefits to the recipient (private practitioner, persons employed with the private practitioner) is not exercised with the view of favouring the donor on the detriment of other entrepreneurs or consumers. The later represents an act of unfair competition which could be sanctioned, under the Law on Trade, within the frame of litigation for compensation of damages occurred therefrom as a result of direct action of the competitor, professional trade associations or consumers i.e. their associations.

Another issue is the value of such donations. In case of gifts in kind there is no statutory threshold nor any guidance in terms of neither the purpose nor the actual type of the gift. Interpretation of another provision of the Law on Trade governing unfair competition may only serve as a rough guideline, as it explicitly forbids winning consumers by giving or promising rewards or other financial benefits of value which excessively exceeds usual value of such goods / services. However, permissible value shall be determined on the case-to-case basis as it can be expected that any assertion that donation was made with the view of influencing concerned practitioners’ decision on the choice of medicinal product of one manufacturer over its competitors shall have to be supported with valid evidence.

There is also no explicit provision determining if gifts in kind...
should be relevant to the recipient’s work or their purpose.

One should not disregard ethical standards which all health professionals must observe: under the Code of Ethics of the Croatian Medical Chamber doctors must endeavour to protect their professional reputation and independence avoiding self-assertiveness and association with commercial activities for personal gains – behaviour contrary to quoted provision qualifies as breach of professional Code of Ethics and could be sanctioned accordingly in disciplinary proceedings before the Medical Chamber.

Giving gifts (in money and kind) to medical practitioners employed with the health institutions (public hospitals, clinics etc.) should be even more scrutinised since, under the provisions of the Law on Health Protection, any medical professional who takes part in medical-related transaction for her/his own account without employer’s approval is deemed to be in grave breach of her/his obligations under employment contract (this is also valid for health practitioners employed with the private institutions).

Permissibility of donations in money and in kind which are given to health professionals who occupy positions/are employed with the government and governmental agencies must be observed under the Law on Prevention of Conflict of Interest in Performance of Public Duties (Official Gazette No. 163/03, 94/04) which, as a rule, prohibits any donations (in money, in kind or in services) which put or which may put the recipient in the position of dependence or create a counter-obligation. Quoted law is applicable if concerned recipients occupy certain rank or position in the concerned governmental bodies. Only gifts of symbolic value not exceeding approx. 68 EUR from the same donor can be retained by such individual. Any donation exceeding mentioned value must be returned, declared in an appropriate register and is deemed to be the property of the state. Breach of these provisions by the concerned state official is sanctioned in proceedings before special committee construed under the mentioned law.

Finally, as any payment with corrupt intention, donation could be subject to criminal enforcement for charges of giving/receiving bribery which, under the Croatian Criminal Law, can be committed by anyone who is giving or promising to give a gift or other benefit to the official or responsible person as well as anyone soliciting in such offence. The recipient must be an official or responsible person and the payment must be induced to induce the recipient to misuse her/his official position whereby the payer/donor would obtain improper advantage.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

It is possible to give donations in kind and in money to institutions provided that such donations are made in a transparent manner, without return-of-favour close, whether written or silent, and in line with all other rules on contracting and fair business. In addition to that, prerequisite for receipt of donations by health institutions in Croatia is approval of the donation by the Ministry of Health.

Payment (as well as giving/promising money or other pecuniary benefits) for prescribing is prohibited.

4.5 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

The rules on advertising of medicinal products in Croatia do not deal with this particular issue. These type of arrangements are primarily regarded as trade arrangements in which defining of prices, margins and discounts is at the free disposition of the parties observing, of course, statutory pricing rules in determination of the wholesale prices, rules on fair competition, antitrust laws and other applicable laws.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

The rules on advertising of medicinal products in Croatia do not deal with this particular issue. This particular situation clearly raises legal concerns discussed within this section of report.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The rules on advertising of medicinal products in Croatia also do not deal with this particular issue.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Croatian laws analysed for the purpose of this review do not provide rules for allowed sources of education of health professionals. To that extent, there are no obstacles for a pharmaceutical company to act as sponsor of educational events/provider of educational materials thus contributing to a statutory obligation of health professionals in Croatia for gaining of the continuous education.

By-law explicitly provides that such activity of the company (and other players in the distribution chain) is allowed for as long as the materials/discussions at conferences and meetings amount to a scientific/educational exchange of information. Promotional content in/at such meetings is not prohibited, but it should be auxiliary to the main purpose of the education.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

Offering of hospitality to health professionals raises concerns similar to those explained in question 4.2 above and should be observed on the basis of each individual case taking into consideration all circumstances involved.
5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Permanent education and continuous follow-up of recent developments in medical science for the purpose of procurement of quality, state-of-the-art service is mandatory requirement addressing all doctors under all structural laws and professional rules in Croatia, including Code of Ethics. It is, therefore, expected from doctors to attend scientific meetings. Since most scientific meetings/lectures and similar events are not directly related to the promotion of specific medicinal products (even if sponsored by the pharmaceutical industry, those should preserve scientific rather than exclusively promotional tone under the By-law) it is possible - under transparent arrangements with the concerned individual/institution (see hereabove, under question 4.2) - to cover the expenses connected therewith.

As for the payment for the time of the attending doctor, the answer depends upon her/his actual degree of participation. If the participation is passive, merely as a member of the audience, then the same considerations raised under question 4.2 above must be observed when contemplating any payments to attending doctors. However, if the doctor’s role at the meeting is active i.e. if she/he is also a speaker, a reasonable honorarium for use of copyrighted work is allowed.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

A pharmaceutical company shall be held responsible to the extent that the relationship between the respective company and healthcare professional(s) would be qualified and ruled as non-compliant with the Law, By-law and numerous other sources of law that may be taken into account. Numerous legal issues may be raised by regulators, prosecutors and Code officials, for example, whether meetings are used as illegal inducement to prescribe or use the expenses connected therewith. As for the payment for the time of the attending doctor, the answer depends upon her/his actual degree of participation. If the participation is passive, merely as a member of the audience, then the same considerations raised under question 4.2 above must be observed when contemplating any payments to attending doctors. However, if the doctor’s role at the meeting is active i.e. if she/he is also a speaker, a reasonable honorarium for use of copyrighted work is allowed.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

Sharing of one’s qualified professional knowledge/experiences - especially in cases where concerned individuals are professionals renowned for their expertise and experience in the particular field of medicine or profound knowledge of other topics of interest for a health sector - is allowed in both, scientific and expert circles (at meetings, lectures, participation in advisory bodies and other types of activities) if done in a transparent manner and following proper procedure.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

As mentioned above, payments to doctors for their active participation in various activities requiring their professional knowledge/experience would be possible. As already explained, it is required that all such activities have genuinely scientific content and that the payment is justified with regard not only to the actual services provided but also with regard to constraints mentioned in the question 4.2 above.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

The rules on advertising of medicinal products in Croatia also do not deal with this particular issue.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

It is possible to advertise non-prescription medicines to the general public.

By-law sets out that the following information must be provided:
- name of the medicinal product i.e. non-proprietary name of active ingredient(s) in case the product contains only one active ingredient;
- indication of use and necessary information for proper use;
- instruction for a patient to read carefully the instructions contained in the package, the outer package or container of the product; and
- wording: “For information on indications, precaution measures and side effects consult your doctor or pharmacist”.

Advertising must not be misleading and it must be clearly visible that it is an advertisement for a medicinal product. Advertising to the general public must not use the following statements or implications:
- that the product does not posses side effects;
- that the product guarantees the success of treatment of disease;
- that the product is undoubtedly better than another medicinal product;
- that taking the product prevents from medical examination, advice or operation; and
- that the product is granted with the marketing authorisation;
- that non-taking of the product may negatively impair the health (except when such claims are given within the public health campaigns under the Law on Protection against Contagious Diseases);
- that the product is, due to its natural origin, especially tolerable and effective;
- that the product is food, cosmetic or other common product;
- that the product is granted with the marketing authorisation;
- that the product prevents from medical examination, advice or operation; and
- that the prescribed product should be replaced with the other product.

Advertising to the general public is not permitted if:
- contains information on listing of the product to the reimbursement list (except when such claims are given within the public health campaigns under the Law on Protection against Contagious Diseases);
- contains recommendations of health professionals or scientists;
- contains recommendations of celebrities who might influence the use of the product;
- uses history of disease or simulation of diagnostic procedures that might lead to erroneous self-medication or self-diagnosis;
- uses inappropriate, disturbing or misleading statements and visual representations of changes in human body caused by...
disease, injuries or manifestation of certain product;
- uses children depicted as taking concerned product or
  otherwise using the product or presenting products within the
  reach of children without presence of grown-ups;
- uses statements or conclusions on efficacy of products which
  are subject to clinical trials in Croatia or abroad;
- is mainly directed to children; or
- displays the name of the pharmacy or other point of sale.
When advertising medicinal products to the general public it is
prohibited to collect personal data on patients, their health conditions,
diagnosis, therapy and the medications they were prescribed.

6.2 Is it possible to advertise prescription-only medicines to
the general public? If so, what restrictions apply?

Advertising of prescription-only medicines to general public is
expressly prohibited.

6.3 If it is not possible to advertise prescription only medicines
to the general public, are disease awareness campaigns
permitted, encouraging those with a particular medical
condition to consult their doctor, but mentioning no
medicines? What restrictions apply?

The Law qualifies rendering information on medicinal products as
permitted activity. Any impartial and objective providing of
information to the public on diseases, their prevention and available
treatment options is qualified as permitted rendering of information.
This, clearly, opens the gate to introduction of public disease
awareness campaigns that could be supported also by
pharmaceutical companies. So far, under the applicable By-law,
only activities of public health sector targeted at promoting of
immunisation, seroprophilaxis and chemoprophilaxis in accordance
with the programme passed by the MoH in implementation of the the
Law on Protection against Contagious Diseases was allowed.
As at the date of this report, however, MoH still has not passed a by-

6.4 Is it possible to issue press releases concerning
prescription only medicines to non-scientific journals? If
so, what conditions apply?

No. Advertising of prescription-only medicinal products to the
public in general is forbidden by the Law. This prohibition
addresses also releases in a press of non-scientific nature.

6.5 What restrictions apply to describing products and
research initiatives as background information in corporate
brochures/Annual Reports?

The rules on advertising of medicinal products in Croatia also do
not deal with this particular issue.

6.6 What, if any, rules apply to meetings with and funding of
patient support groups, including any transparency
requirement as regards the recording of donations and
other support in corporate reports?

The rules on advertising of medicinal products in Croatia also do
not deal with this particular issue.

7 The Internet

7.1 How is internet advertising regulated? What rules apply?

Internet advertising of medicinal products is not regulated in the
concerned laws and regulations. In other words, the same rules are
expected to apply for the Internet as for other forms of advertising.

7.2 What, if any, level of website security is required to ensure
that members of the general public do not have access to
sites intended for health professionals?

By-law expressly provides that the access to health professionals-
targeted information must be limited to health professionals. The
precise method that would prevent an access of audiences other
than health professionals are not given. In such legal environment,
decision on the level of website security (and the contents of the
websites) are left to the discretion of the respective pharmaceutical
company or other entity.

7.3 What rules apply to the content of independent websites
that may be accessed by link from a company sponsored
site? What rules apply to the reverse linking of independent websites to a company's website? Will the
company be held responsible for the content of the independent site in either case?

No guidance on this issue is currently given in the available sources
of law on pharmaceutical advertising.

7.4 What information may a pharmaceutical company place
on its website that may be accessed by members of the
public?

Internet advertising of medicinal products is not regulated in the
concerned laws and regulations. In other words, the same rules that
apply to advertising to general public are expected to apply on the
information intended for general public placed on the Internet.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of
medical devices in Croatia?

The same rules apply to medicinal devices as the ones relevant for
medicinal products.

8.2 Are there any restrictions on payments or hospitality
offered to doctors in connection with the promotion of a
medical device?

There are no specific rules. Therefore, we refer to our answers
given above under section 5.
9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

On its session held on 21 July 2007 Croatian Parliament adopted new Law on Medicinal Products which is generally harmonised with the current EU legal framework. Unlike former Law, the new Law differentiates between advertising and rendering information on medicinal products. The more specific rules governing advertising of / rendering information on medicinal products shall be provided in special by-laws drafting of which falls within the competency of Croatian Ministry of Health. It is, therefore, expected that in the foreseeable future Croatia shall have the new set of rules on pharmaceutical advertising which shall replace the currently applicable By-law.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

As mentioned above, given the fact the new Law provided an instructive deadline for passing of the new by-law on pharmaceutical advertising (as well as a number of other by-laws with a view to adjust their provisions with the Law) of one year following the date of effectiveness of the Law, it is expected that the Ministry of Health shall soon put forward proposals thereof.

9.3 Are there any general practice or enforcement trends that have become apparent in Croatia over the last year or so?

Although the laws affecting advertising and marketing of pharmaceutical products have been in place for some time in Croatia, it could be generally stated that no persistent enforcement practice was seen in the past. However, the negative publicity connected with practices of pharmaceutical companies that were exposed in media in the recent years raised public awareness not only of industry’s promotional practices but also the relationship between pharmaceutical companies and health professionals. This, coupled with the fact that the government is trying to reduce spending of public money on pharmaceuticals and medicinal devices and to level Croatian legal framework governing pharmaceutical advertising with that of EU, means that the enforcement activities may soon became more concentrated on pharmaceutical sector.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

There is no code of practice that would be applicable on the national level in Croatia. Croatian Association of Research-Based Pharmaceutical Companies (further referred to as: CARPC) - an association with liaison status of EFPIA - has its own Code of Conduct on Advertising of Medicinal Products (further referred to as: the Code) which takes into account 2006 issue of the European Code of Practice for the Promotion of Medicines of EFPIA. However, the conduct requirements of the Code are binding only to member companies of CARPC.
Snježana Došen started her career after her studies at the University of Zagreb, Faculty of Law in 1994. From 1994 to 1997 Snježana worked as trainee in the law office of Ratko Žurić, Attorney-at-Law where she gained experience in the field of commercial and intellectual property law as well as in general legal practice. In 1997 she was admitted to the Bar and she is a member of the Croatian Bar Association (further: CBA) since. Due to the changing legal environment in Croatia and the necessity for continuous education, Snježana spent a part of her traineeship during 1998 - 2000 working with established UK and German law firms. Snježana is a solicitor in Law Firm ŽURIĆ I PARTNERI. A considerable part of Snježana’s practice is focused on advising clients in pharmaceutical law and on intellectual property matters. Snježana appears before the regulatory authorities and courts on behalf of major players in the pharmaceutical industry and she is involved in the work of the Ethical Committee of Croatian Association of Research-Based Pharmaceutical Companies.

Žurić i Partneri ("ZiP") is one of the leading law firms in Croatia in the field of general commercial and corporate law, banking- and financial law, labour, real estate, litigation and arbitration, intellectual property, pharmaceutical law and other areas of law typically relevant for corporate clients. For many years ZiP has acted as the chief local legal advisor for a number of international corporations, of which some are the global leaders in their respective businesses. Established in 1992, the firm has 20 lawyers and close to thirty support employees. Our offices are in Zagreb, but the firm is also a correspondent firm for a number of law firms in London, New York and Brussels. We have also developed an efficient network of correspondent offices throughout Croatia, Slovenia, Bosnia and Herzegovina and Serbia and Montenegro.