

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2006

A practical insight to cross-border Pharmaceutical Advertising work



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1 General - Medicinal Products

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

Generally and specifically: Act No. 40/1995 Coll., the Advertising Regulation Act, as amended (last amended in Act No. 25/2006 Coll.).

Indirectly and marginally: Other laws and regulations (e.g. Act No. 79/1997 Coll., on Medications, as amended (last amended in Act No. 309/2002 Coll.).

Professional Ethics Codes.

1.2 How is “advertising” defined?

Advertising is defined as every form of communication, presentation, or display disseminated through any media, that is primarily intended to promote business activity, the consumption or sale of goods, the construction, lease, or sale of realties, the sale or use of obligations, the provision of services, and/or trademark promotion, if not stipulated otherwise by law.

1.3 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?

There is no general requirement for prior approval; however, this can result from the application of certain specific laws (for example in the case of financial services).

1.4 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?

Yes, the authorities do have powers to stop the further publication of the advertisement in some cases.

As a general rule, there is a right of appeal, and if not, it is possible to apply for judicial review.

1.5 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?

The maximum penalty is a fine of 2,000,000 CZK (two million Czech Crowns).

As regards unfair competition, please see the answer immediately below.

1.6 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Third parties (entrepreneurs, consumers, associations of consumers) can raise a claim and take legal action on the basis of unfair competition.

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?

It is possible to provide health professionals with information about unauthorised medicine that is general and is not promotional. The information on unauthorised medicines may be discussed or made available at scientific meetings. Sponsorship is not possible, since this is always considered as advertisement and is therefore prohibited.

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

It is possible to publish information that is not promotional but only in scientific/professional publications; there are no restrictions in that case.

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

It is possible to issue press releases only to professionals and only provided that the information contained is not promotional. It is prohibited to issue press releases to general audiences about medicinal products which are not yet authorised (except for over-the-counter medicines). A more precise answer would depend on various different circumstances.

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

Under various circumstances, it may be considered as advertisement, and a circumvention of the Advertising Regulation Act. Such information may only be sent to a health professional upon his or her specific request for information about a specific medicinal product. The information provided should not be promotional.

There are also limitations arising from the direct mailing regulation.

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?

It may be considered as advertisement and a circumvention of the law in certain circumstances. See the answer to question 2.4 above.

3 Advertisements to Health Professionals

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

All advertisements directed to health professionals must contain essential, up-to-date information; the information must be sufficient and capable of being proved. All advertisements must contain essential information about the medicinal product including the date of its authorisation and most recent version thereof, and information about the dispensing of the medicinal 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?

There is no such specific requirement; as regards the comparative claims, please see the answer to question 3.3 below.

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 your country?

Comparator advertisements are regulated very strictly in Czech Republic. Comparator advertisements of medicines may be provided to professionals only.

General rules for comparator advertisements are provided in the Commercial Code, which stipulates that comparator advertisements:

- should not mislead;
- may compare only goods or services satisfying the same needs or serving the same purpose;
- may compare only the relevant features of goods or services;
- should not create a risk of mistaken identity of a product (service); and
- should not be defamatory.

Comparison to an unauthorised medicinal product may be considered as improper use of another's goodwill and it is also contrary to the requirement to compare only goods or services satisfying the same needs.

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

There is no specific regulation. If the scientific papers or proceedings are promotional they should comply with the general rules governing advertisements.

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)?

There is no general ban. It is possible to alert a reader to a specific product provided that the advertisement complies with general legal requirements. It may be contrary to the rules governing advertisements of pharmaceutical products under certain circumstances.

4 Gifts and Financial Incentives

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

Yes, it is possible provided certain legal conditions are met. Samples may only be provided to professionals qualified to prescribe medicinal products. A limited number of samples of each product may be supplied in any one year to one recipient. Samples must be no larger than the smallest presentation available for sale. Samples must be marked with wording indicating that they are not for sale. Samples must only be supplied in response to a written, signed, and dated request of a person who is qualified to prescribe medicinal products.

Providing health professionals with samples of products, and the activities below under questions 4.2 - 4.7, are considered forms of advertisement.

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

Yes, it is possible provided certain legal conditions are met. The price of the gift or donation should not exceed the amount of 1,500 CZK (one thousand five hundred Czech Crowns). The gift (donation) must be relevant to the medical practitioner's work.

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?

Yes, it is possible provided that this is not addressed directly to a medical practitioner. It may be considered a breach of law under certain circumstances, especially if the gift (donation) is aimed at acquiring competitive advantage.

4.4 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?

There is no general ban; however, in certain circumstances, it may be contrary to the general rules governing unfair competition and economic competition and it may be contrary to the Advertising Regulation Act, especially if the discount is promotional.

4.5 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?

See the answer to question 4.4 above.

4.6 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?

Generally, it is possible. However, the medicines and their sale are very strictly regulated in the Act on Medications. Offering a refund scheme would be contrary to the regulation provided in the Act on Medications.

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

Sponsorship is a kind of advertisement. It is possible for pharmaceutical companies to sponsor continual medical education provided that the sponsorship is reasonable.

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?

See the answer to question 4.7 above; the hospitality offered to health professionals must be reasonable.

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?

Yes, it is possible if done in a reasonable manner. Restrictions may arise from the doctor's employment.

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

Generally it is possible; restrictions may arise from the doctor's employment.

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

Generally it is possible; restrictions may arise from the doctor's employment as above. As regards clinical trials, it is necessary to comply with the Act on Medications and relevant Decree. If the post-marketing surveillance study is promotional the doctor's activity may be considered as circumvention of the Advertising Regulation Act.

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

This is not generally prohibited. It would depend on the relevant circumstances. If the market research is promotional it may be regarded as circumvention of the Advertising Regulation Act.

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?

Non-prescription medicines may be advertised to the general public.

The advertisement should contain:

- Information that the product is a medicine.
- The exact name of the medicine.
- Information necessary for correct use of the medicine.

The advertisement must not:

- Suggest that the effects of the medicine are guaranteed, without side effects, or better than or equivalent to another medicine or treatment.
- Suggest that taking the medicine will enhance health.
- Suggest that health may be adversely affected by not taking the medicine.
- Be directed to people under the age of 15.
- Include a recommendation by a scientist, health professional, or well known person if this could encourage the consumption of the medicine.
- Suggest that the product was a food, cosmetic, or other consumer product.
- Suggest that the safety or efficacy of the product was

due to its natural character.

- By use of a case history, lead to erroneous self-diagnosis.
- Refer in improper, alarming, or misleading terms, to claims of recovery.
- Use improper, alarming, or misleading representations of the human body.

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

This is prohibited by the Advertising Regulation Act.

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?

Disease awareness campaigns are permitted, provided that the information is not promotional. The statements must not be made for the purpose of encouraging people to ask their doctors to prescribe a particular medicine. The information must not contain a concealed advertisement of a particular pharmaceutical product.

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

In our opinion, this may be considered as circumvention of the general ban on advertisements of prescription-only medicines.

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

There are no specific restrictions.

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?

In our opinion, general rules on accounting are applicable.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Act No. 480/2004 Coll., on Certain Services of Information Companies, as amended by Act No. 444/2005 Coll. General laws governing the Internet presentation.

Pursuant to the Act above, a natural or legal person is permitted to make use of a customer's electronic contact information (email address) for direct marketing when prior consent can be demonstrated. Customers must always clearly and distinctly be given the choice to object, free of

charge and in an easy manner, to such use of their electronic contact details when they are first collected, and with each message in the case of customers who have not initially refused such use. The sending of unsolicited business communications by electronic means, i.e. spam, is prohibited. Sending unsolicited business communications is permitted only with the demonstrable prior consent of the addressee. Sending emails for the purpose of dissemination of business communication is prohibited if i) the communication is not clearly and distinctly entitled as business communication; ii) it dissimulates or conceals the identity of the sender; and/or iii) it is sent without a valid address to which the addressee could directly and effectively give notice that it does not wish to receive any more business information.

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?

There is no specific technical regulation.

8 General - Medical Devices

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

Primarily and specifically: Act No. 40/1995 Coll., Advertising Regulation Act, as amended (last amended in Act No. 25/2006 Coll.).

Partially and additionally: Other laws and regulations.

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

Yes, there are restrictions similar to those in connection with the promotion of medicines.

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?

An amendment to Act No. 40/1995 Coll. (the Advertising Regulation Act) became effective on January 26, 2006. Directive 2001/83/EC of the European Parliament and European Council, on the Community Code relating to medicinal products for human use, has been partially implemented by this amendment.

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

An amendment to the Act on Medicines is expected to become effective next year. It may have an impact on the advertising of medicines.

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