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Global Legal Group

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work

Published by Global Legal Group with contributions from:

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1 General - Medicinal Products

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

The advertising of pharmaceuticals is regulated by the Advertising Law (adopted on 20 December 1999) and the secondary legislation, i.e., by the regulations of the Cabinet of Ministers No.167 "Order of Advertising of Pharmaceuticals and Order how the Manufacturer of Pharmaceuticals is Entitled to Provide the Free Samples to Healthcare Professionals" (adopted on 6 March 2007, effective as of 10 March 2007). The members of Association of International Research-based Pharmaceutical Manufacturers (AFA) which is incorporated in Latvia apply the Code of Practice on Promotion of Medicines. The Code is developed in accordance with the respective code of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

1.2 How is "advertising" defined?

"Advertising" is considered to be any kind of announcement or activity in order to facilitate the prescription, delivery, sales and use of pharmaceuticals, including:

(i) advertising of pharmaceuticals to the public;

(ii) advertising of pharmaceuticals to the healthcare professionals;

(iii) provision of information by the person authorised to advertise a pharmaceutical (medicinal representative);

(iv) distribution of the samples of pharmaceuticals;

(v) inducement to prescribe or distribute any pharmaceutical by offering financial or other kind of remuneration except for cases the value of such inducement is insignificant; and

(vi) covering of the expenses (including travel and accommodation) of the professionals participating in the advertising or scientific events.

The following activities are exempted from the scope of statutory acts regulating the advertising of pharmaceuticals:

(i) labelling and packaging leaflets of pharmaceuticals, unless they are used for advertising purposes;

(ii) correspondence which has no advertising character and answering to questions related to pharmaceuticals;

(iii) informative announcements, e.g., on changes of packaging, adverse effects, sales catalogue without pharmaceuticals advertising materials;

(iv) announcements on the health status and diseases if they contain no indication to particular pharmaceuticals; and

(v) information provided by the specialist to individual patient on the requested pharmaceutical.

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?

There are no particular statutory requirements governing compliance policy by companies.

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?

Approval of the State Agency of Medicines (hereinafter - "SAM") must be obtained prior to the communication of the advertisement. The applicant should submit to the SAM the respective application supplemented with the text, pictures, video and audio demonstrating the content of the advertisement, as well as the sample of the advertisement data carrier and the confirmation of the information which is included in the advertisement but is not mentioned in the registration documentation of the pharmaceutical. The SAM surveys the submitted documents and makes a decision within one month after reception of the application. The approval of the SAM is valid for an indefinite term unless the certain changes should be made in the advertisement. The approval of the changes shall be carried out using the same procedure as the approval of the advertisement. In case the SAM rejects the application, the applicant is entitled to appeal in the court the decision of the SAM.

In case of a comparative advertisement the SAM provides information on the advertisement in its website. The holder of the market authorisation of the pharmaceutical which is directly or indirectly compared in the respective advertisement is entitled to examine the materials of the advertisement and submit its opinion to the SAM within two weeks.

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?

The provider of the advertisement may deem that the advertisement is compliant with the statutory requirements if the SAM has

approved the respective advertisement. Therefore, in general the SAM should not consider the advertisement as non-compliant during its communications. If an unapproved advertisement is communicated to the public general, the Health Inspection (hereinafter - "HI") may order to cease further communication. In accordance with the requirements of the Advertising Law in case of an incompliant advertisement, the HI may order:

1) the provision in the advertisement of additional information which is significant;
2) the exclusion of some element(s) of the advertisement (e.g. information, picture, sounds or other special effects);
3) the discontinuance of further communication of the advertisement;
4) the recall the advertisement; and
5) the initiation of the administrative prosecution on the infringement of the law.

The decision of the HI may be appealed to the court within one month after its adoption.

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?

The supervision of the compliance of the statutory requirements is carried out by the HI. The HI may impose an administrative penalty of up to 700 EUR for individuals and 1,400 - 7,000 EUR for legal entities for failing to comply with the pharmaceutical advertisement statutory requirements. Pursuant to the increasing amount of advertising taking place in less traditional media (i.e. internet, e-mail) and large scale short-term advertising campaigns (i.e. information leaflets), the enforcement is less strict in the said fields than in traditional media (i.e. TV, radio, newspapers, magazines). The competitors may take direct actions through the courts if the advertisement has caused any damages (e.g. losses, damage to reputation) other than only incompliance with the statutory acts regulating the advertisement of pharmaceuticals. Otherwise the courts may be involved only as the appeal institution for the decisions of the HI.

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 competent authorities investigate matters drawn 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?

The competent authorities supervise only compliance with the statutory requirements and investigate the matters concerning the statutory requirements. The supervision of the self regulatory acts is carried out by the organisation which has set the respective self regulatory act. The authorities (in particularly, the HI) are entitled to investigate the matter upon their own initiative. Furthermore, the adverse finding of the self-regulatory body may serve as the inducement to commence the investigation by the HI.

1.8 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?

In case of unfair competition the authorities (the SAM, HI) and the concerned person are entitled to submit the respective application to the Competition Council or to the court. The Competition Council is also entitled to initiate the investigation on its own initiative.

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 pharmacy advertising laws determine certain actions which are not classified as an advertisement; therefore, they are not regulated by the pharmaceutical advertisement regulation (see question 1.2). Consequently some actions, e.g. informative notices, as well as the distribution of sales catalogues and price lists where therapeutic indications of pharmaceuticals are not included may be used to inform health professionals on the unregistered pharmaceutical.

Due to the broad definition of advertising which refers to any kinds of activities which aim to promote the use of pharmaceuticals, discussions on the unregistered pharmaceutical in scientific meetings may be considered as an inducement to use the pharmaceutical; therefore, it can be prohibited, although the issue is not specifically regulated by Latvian law. The qualification of the advertising activity does not depend on the relationship of the sponsor of the scientific meeting to the unregistered pharmaceutical.

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

As mentioned in question 2.1 the information on the unregistered pharmaceutical may be included in sales catalogues and price lists where therapeutic indications of pharmaceuticals are not listed. Other types of publications may inevitably lead to the conclusion that the direct or indirect objective of the publication is the promotion of the prescription or use of the respective pharmaceutical and is ultimately prohibited.

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

The issuance of a press release relating to an unregistered pharmaceutical is likely to be considered to be advertising. Taking into account the prohibition to advertise unregistered pharmaceuticals the press release relating to an unregistered pharmaceutical shall be considered illegal.

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

The sending of information on an unregistered pharmaceutical

might also be considered as an activity to promote the prescription/use of the pharmaceutical. In accordance with the statutory requirements, such advertisement activities may be carried out only regarding authorised pharmaceuticals.

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?

The sending of information on an unregistered pharmaceutical to institutions for budget planning as far as it facilitates the prescription/use of the pharmaceutical most likely will be deemed to be advertising. Taking into consideration the statutory prohibition to advertise unregistered pharmaceuticals, the sending of such information might be considered prohibited.

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?

There are no specific regulations concerning the involvement of health care professionals in market research; nevertheless, such activities may be qualified as the advertising of the respective pharmaceutical and, consequently, might be deemed prohibited due to the general prohibition to advertise unregistered pharmaceuticals. There are no guidelines, regulating specifically market research of medicinal products.

3 Advertisements to Health Professionals

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

In advertisements directed only to the health professionals at least the following information shall be included:

(i) important information on the pharmaceutical in accordance with the Summary of Products Characteristics;

(ii) information on whether the pharmaceutical is an OTC or prescription only pharmaceutical; and

(iii) the date when the advertisement was last confirmed by the SAM.

Only the title of the pharmaceutical may be indicated in an advertisement to health professionals if the advertisement is intended solely as a reminder of the previously communicated advertisement.

In order to enable the professional to evaluate the therapeutic influence of the pharmaceutical, the information included in the advertisement must be precise, updated, verifiable and complete.

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 statutory requirement to supplement the comparative advertisement with data on clinical trials. Nevertheless, taking into account the obligation of the provider of the advertisement to ground the comparative claim in case the advertisement is challenged to the HI or court it would be recommendable to have the respective documentation at the disposal of the provider of the advertisement.

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 Latvia?

Detailed regulation on comparative advertisements is set by the Advertisement Law (adopted on 20 December 1999). There is general prohibition to use firm, brand names and other identifying marks of other company without its consent. Nevertheless, in accordance with the mentioned statutory act the use of another company's brand name may take place in advertisement as far as it complies with following principles:

(i) the compared products relate to the same category and kind;

(ii) the impartial comparison of the verifiable features of the products is carried out;

(iii) no confusion regarding the comparable products of the advertiser and the competitor is caused;

(iv) the competitor, its personal features, products or brand names are not discredited; and

(v) the goodwill of the competitor, its products or brand names are not used unfairly.

There might be some argumentation in favour of the inclusion of the unregistered pharmaceutical of the competitor in the comparative advertisement (because the comparative advertisement is not intended to promote the product of the competitor). Nevertheless, most likely the HI would sustain the strict application of the prohibition to promote the unregistered pharmaceuticals; therefore, it might be deemed illegal.

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

There are no specific provisions regarding distribution of scientific papers and/or proceedings of congresses to health care professionals and the content of the both. Nevertheless, the organiser is obliged to inform the HI on: (i) the exhibitions; (ii) seminars connected with the advertisement of pharmaceuticals; (iii) conferences; (iv) congresses; and (v) other events seven days prior to the event. The organiser shall provide to the HI the schedule of the event indicating the place and time, organisers, sponsors, targeted participants, type of the estimated advertisements and other information related to pharmaceuticals, as well as the persons responsible for the advertisement.

The actions taken by the HI upon reception of the said information varies on a case by case basis. Usually the HI does not take particular prohibiting or controlling actions; although, such situation may not be excluded.

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)?

The pharmacy advertising laws determine that advertisements to the general public should be clear that:

(i) the distributed information is an advertisement; and

(ii) the advertised product is a pharmaceutical.

Therefore, the use of the teaser-type advertisement campaigns may be considered illegal, unless the first advertisement(s), which draws the attention of the public, will be compliant with the regulatory requirements of advertising of pharmaceuticals.

4 Gifts and Financial Incentives

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

The samples of products shall be provided by the medical representatives. The samples may be provided only to the persons authorised to prescribe the respective pharmaceuticals. The following restrictions are applied:

(i) the sample must contain the smallest amount of the respective pharmaceutical, which is provided for sales;

(ii) the sample must be labelled with the mark "Free sample - not for sale";

(iii) the Product Information Leaflet must be provided;

(iv) the sample must not contain isotretionin and the psychotropic and narcotic substances which distribution is controlled in Latvia;

(v) a respective written application of the beneficiary must have been received prior to the delivery of the free samples;

(vi) the provider and the beneficiary must form and maintain the inventory and control the register of the free samples; and

(vii) a maximum of 1,000 free samples of the respective pharmaceutical may be distributed for all persons authorised to prescribe the pharmaceutical in total during a year.

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

There is general prohibition for the professionals to accept any kind of remuneration, unless it is connected with/usable in medical or pharmaceutical practices and its value is insignificant. The said prohibition shall be applied and respectively interpreted for all other kinds of inducements applied in the practice and described below.

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?

The donation of the equipment to hospitals in favour of prescription or distribution of the pharmaceuticals is prohibited, unless the equipment is connected with/usable in medical or pharmaceutical practices and its value is insignificant. There are no precise criterions for the evaluation of the insignificance of the value. Therefore, the decision of the HI or court upon the claim would be taken on case by case basis.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

The provision of medical, educational goods or services to the health professionals may be qualified as remuneration in favour of prescription/distribution of pharmaceuticals. Such promotion of pharmaceuticals is prohibited, unless the value of goods and services provided is insignificant.

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 pharmaceuticals advertising statutory requirements prohibit the advertising when pharmaceuticals are proposed as gifts or compensation for purchase of certain good or service, or where gift or discount is proposed for the purchase of a pharmaceutical; although, it is not prohibited to offer discounts in general. Nevertheless, considering the obligation of the importer/manufacturer to declare the price of the pharmaceutical to be distributed in Latvia, any deviation of such price whether upwards or downwards might be considered as breach of the price regulations. Furthermore, the discounts may be also considered illegal due to the prohibition for the professionals to accept remuneration in favour of prescription/distribution of the pharmaceuticals.

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?

It is not prohibited to offer and provide additional medical or technical services or equipment. However, in accordance with the statutory requirements the respective services or equipment shall be of insignificant value. It is difficult to set more precise amounts which might be considered as allowed due to the lack of the respective statutory prescriptions. The medical or technical equipment may be provided for clinical trial needs in case the hospital does not posses such equipment. After the completion of the trial the equipment occasionally is left to the hospital.

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?

There are no specific legal prohibitions in regard to the refund schemes. However, in order to define the legality of such refunding schemes the context of the offered refund scheme shall be considered. The decision of the HI or court would be taken on a case by case basis.

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

There are no specific prohibitions in regard to the sponsorship of continuing medical education. Although the sponsorship lacks the direct link with the commitment of the professional to prescribe the pharmaceutical, the sponsorship may be deemed to be illegal due to the prohibition for the professionals to accept any kind of remuneration.

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?

The general regulation on advertising of pharmaceuticals is applied

to the offering of hospitality to professionals. The expenses covered for the professionals shall be of a representational nature. The expenses shall be covered for events of a professional and scientific nature and strictly limited and connected with the main objective of the event. The statutory requirements do not provide additional restrictions on the place and/or country where the event will take place.

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?

The statutory regulation provides general provisions, namely, only representative expenses for events of a professional and scientific nature are allowed. The travel, accommodation and enrolment fees may be considered as allowed if they are limited and connected with the objective of the respective event. Furthermore, the payment to the professional for his/her time may be interpreted in a very broad sense which does not demonstrate the undoubted professional and scientific nature of the expenses as required by law; thus, most likely it will be considered illegal.

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?

The primary responsible person for the content of the scientific meeting (professional event) is the organiser. The organiser is obliged to inform the HI providing the information on the event seven days prior to the event (for details see question 3.4). Therefore, if the pharmaceutical company organises the event it will be held responsible for the content, schedule and other issues related to the event and the advertisement of pharmaceuticals. The general requirement to submit the advertisement to the SAM for authorisation is not applied for materials used in conferences, meetings and other events; nevertheless, this does not exclude the applicability of other statutory restrictions regarding the advertising of pharmaceuticals.

When providing hospitality arrangements to individual professionals the pharmaceutical company should comply with statutory requirements regarding restrictions in providing any kind of remuneration in favour of prescription/distribution of the pharmaceutical as described in questions 4.1-4.8, as well as the general condition on the covering of the scientific/professional events (for details see questions 5.1-5.2).

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

Professionals may be paid for their expert services. There are no direct restrictions in regard to the fees of the experts; however, the context of the tasks and duties of the professional shall be considered. It must be noted that the participation of the professional in the research or study may be deemed to be the cover of the payments for the prescription/distribution of pharmaceuticals and as such it may be considered illegal. Therefore, the decision of the HI or court regarding the compliance with the law would be taken on a case by case basis.

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

There are no specific legal prohibitions concerning the participation of the professionals in the marketing surveillance studies. Although the mere participation either as participant or the surveyor in the marketing surveillance could not be considered to be distribution or prescription of pharmaceuticals, the context of the market surveillance and consequences shall be considered. Furthermore, in case the market surveillance may be considered as promotional for the certain pharmaceutical the respective market surveillance materials will be deemed to be the advertising materials. Consequently, the authorisation of the SAM shall be obtained prior to the use of the said materials.

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

There are no specific legal prohibitions concerning the participation of the professionals in the market research with or without promotional materials. However, the authorities might qualify the payment to the professional for the participation as the remuneration which is prohibited in accordance with statutory acts. Therefore, the objective and proceeding of the market research is important and it should be carefully assessed in the light of advertising restrictions. Furthermore, the respective promotional materials should be authorised by the SAM prior to the use.

It must also be noted that the advertisement to the public general may not contain the reference to the health professional; therefore, the health professional is prohibited to conduct the market research and distribute the advertising (promotional) materials involving the members of the general public.

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 permitted to advertise non-prescription medicines to the general public. Such advertisement shall comply with the following:

(i) the information provided shall be compliant with the information provided in the Summary of Products Characteristics;

(ii) the information provided shall be impartial (objective) and the qualities of the pharmaceutical is not exaggerated; and

(iii) the advertisement is not misleading.

It is prohibited to advertise to the general public the pharmaceuticals the price of which is partly or wholly compensated from the state budget.

It is prohibited to include the following information in the advertisement of a non-prescription pharmaceutical to the general public:

(i) information which initiates the medical treatment using post services or providing advice in a similar way, and makes the impression that the diagnoses can be made without consultation with a professional;

(ii) information which gives the impression that the effect of the pharmaceutical is guaranteed, the pharmaceutical does not cause any side effects and is on a par with similar treatment methods or other pharmaceuticals or that it is better than same;

(iii) information which gives the impression that the overall health condition of a patient will significantly improve by taking the pharmaceutical;

(iv) information which gives the impression that the health state of a patient will decline if the pharmaceutical will not be taken;

(v) information which only or primarily targets children;

(vi) information which contains references to suggestions of scientists, health care professionals and other well-known persons, which may increase the use of the pharmaceutical;

(vii) information which gives the impression that the pharmaceutical is a food, cosmetic or other consumer good;

(viii) information which gives the impression that the safety and efficiency of the pharmaceutical is guaranteed by its natural origin;

(ix) information on details of a medical history, which may cause the misleading self-diagnose;

(x) information describing recovery of a patient in unsuitable, alarming or misleading terms;

(xi) information which unsuitably, alarmingly or misleadingly describes the transformation of the human body by a disease or injury or describes how the pharmaceutical affects the human body or its parts; or

(xii) information which initiates the purchase of the pharmaceutical because of its price.

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

It is prohibited to advertise prescription-only pharmaceuticals to the general public.

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?

Announcements on the health condition of people and diseases are not qualified as advertisements if they do not contain an indirect indication to pharmaceuticals. Thus, disease awareness campaigns are permitted if the said condition is complied with.

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

In accordance with statutory requirements any announcement distributed by the person who is authorised to advertise a pharmaceutical is qualified as an advertisement. The advertisement of prescription only pharmaceuticals to the general public is prohibited. Notwithstanding the aforementioned, an informative announcement and general information on the pharmaceutical (e.g. changes in the packaging, warnings of side effects as one of the means of a general precaution regarding the use of a pharmaceutical) shall not be deemed to be an advertisement. Therefore, information compliant with the previously mentioned conditions may be published in non-scientific journals. However, it must be stressed that any announcement is considered to be an advertisement if it is indented to promote the prescription, distribution, sales and use of the pharmaceutical. Thus, the context of the press release and the content shall be carefully considered. The decision of the HI or court would be taken on a case by case basis.

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

Information on pharmaceuticals and research initiatives included in corporate brochures/reports is not considered to be an advertisement due to the fact that the objective of the provision of the said information is not being the promotion of the particular pharmaceutical. Nevertheless, the context of the provided information and further distribution of the corporate brochures/reports shall be considered.

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 meetings and funding of the patient support groups and/or other non-governmental organisations is not regulated by the pharmacy advertising laws, unless the information disseminated and/or the financial means assigned are intended for the promotion of pharmaceuticals. The usual statutory requirements for the accountancy and drafting of the corporate documents are applied for both the donator and beneficiary regarding the donations and other contributions.

7 The Internet

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

Advertisements on the Internet are not intensely regulated. For advertisements distributed via the Internet the same statutory restrictions and provisions as for other types of media apply. The only specific provision is the obligation of the provider/distributor of the advertisement to ensure that the general public may not access the specific information intended only for health care professionals.

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?

The statutory acts do not set particular website security levels to restrict the access of the general public to information resources intended for health care professionals. The provider/distributor of the advertisement is responsible for ensuring that the specified information is accessible only by the professionals.

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?

The pharmaceutical advertising regulations do not elaborate on the other content of the website where the pharmaceutical advertisement is placed, as well as on the reverse linking to and from the company's website; thus, no particular requirements shall be complied with in this regard. In general, the provider of the pharmaceutical advertisement would not be held responsible for the content of the independent site; nevertheless, the particular context of the site shall be of importance, e.g., most likely the provider of advertisement would be held

responsible for the content of obvious advertising nature.

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

There are no other requirements for the information provided in the pharmaceuticals advertisement which is distributed/made accessible via Internet; therefore, the same requirements as for information provided in the advertisements circulated via traditional media will be applied (see section 6).

8 General - Medical Devices

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

The regulatory requirements set for the advertisement of goods and services (Advertisement Law, adopted on 20 December 1999) are applied regarding the advertising of medical devices as long as the advertising of the devices does not relate directly or indirectly to the promotion of the particular pharmaceutical. The context of the advertisement, the characteristic and specification of the device shall be considered.

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

The statutory acts do not restrict the payments or hospitality offered to professionals involved in the promotion of medical devices unless they can be deemed to be connected to the concealed promotion of pharmaceuticals. Therefore, the context of the remuneration regarding promotion of devices shall be considered and the decision of the HI or court regarding the compliance with the law would be taken on a case by case basis.

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?

There have been no significant developments concerning the regulation of the advertisement of pharmaceuticals over the last year.

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

Considering the latest plans of the Cabinet of Ministers to reorganise the whole governmental sector, later, in year 2009, it is expected that the SAM will be reorganised, as a result of which the supervision of the pharmaceuticals advertising might be passed to self-regulatory institutions. Currently, it is not possible to provide more details, however, most likely the supervision will be carried out by non-governmental organisation(s) (association) established by the industry representatives.

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

As expected previously the amount of the applications for approval of new advertisements, as well as changes to the approved ones, continued its decreasing trend. Such trend, however, does not reflect the situation with the audio advertisements, amount of which has increased considerably.

Printed advertising remains to be the dominant type of media over video, audio and other communications means.

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

At the beginning of 2008 the members of Association of International Research-based Pharmaceutical Manufacturers (AFA) have adopted the respective amendments and supplementations to the Code of Practice on Promotion of Medicines considering the latest developments to the respective code of the EFPIA as of October 2007. The updated version of the Code of Practice on Promotion of Medicines will enter into force as of 1 July 2008.

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