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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

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 Israel?

The advertising of medicinal products in Israel is regulated by legislation, Health Ministry procedures and codes of ethics, as follows:

Legislation: advertising of medicinal products is not regulated by a specific statute, rather by specific provisions in a number of statutes and regulations.

The Pharmacists Ordinance [New Version], 5741-1981, through the regulations made under it, regulate the registration, marketing and manufacture of medicinal preparations. Advertising of medicinal preparations regulated under the Pharmacists (Sale of Preparation without Prescription, not in a Pharmacy or not by a Pharmacist) Regulations, 5765-2004 (hereinafter: the "**Sale of Non-Prescription Preparations Regulations**") (sections 17-22), and under the Pharmacists (Preparations) Regulations, 5746-1996 (hereinafter: the "**Preparations Regulations**") (sections 28-29).

Advertising of medicinal products on radio and television is regulated, additionally, by specific, detailed legislation such as: the Second Television and Radio Authority (Ethics in Radio Advertisements) Rules, 5759-1999 (rule 11); the Second Television and Radio Authority (Placement of Advertisements in Television Broadcasts) Rules, 5752-1992 (rule 28); the Second Television and Radio Authority (Ethics in Television Advertisements) Rules, 5754-1994 (Chapter 6, Rules 42-43); and the Communications (Telecommunications and Broadcasts) (Advertisements, Service Announcements and Sponsorship Announcements in Designated Channel Broadcasts) Rules, 5764-2004 (rules 60-61).

Likewise, the advertising of medicinal products, like any other advertisement, is subject to the general provisions of the Consumer Protection Law, 5741-1981, and the regulations made thereunder with respect to the advertising of consumer commodities (sections 2 and 7 of the Consumer Protection Law) and with respect to advertisements to minors (section 4 of the Consumer Protection (Advertisements and Methods of Marketing Directed at Minors) Regulations, 5751-1991).

Ministry of Health Procedures: Procedure No. 24 of the Ministry of Health, amended under section 28 of the Preparations Regulations, deals with "advertising of medicinal preparations" and regulates the operations of drug companies vis-à-vis the Ministry of Health with respect to the advertisement of medicinal preparations (hereinafter: "Ministry of Health Procedures").

Codes of Ethics: In October 2004, a Joint Code of Ethics was published by the Israeli Medical Association (hereinafter: the "**IMA**") and organisations representing the drug companies operating in Israel - the organisation of drug companies that deal in research and development - Pharma Israel; the Chemical, Pharmaceutical and Environmental Society of the Manufacturers' Association of Israel, and the Drugs Division at the Federation of Israeli Chambers of Commerce. The Joint Code of Ethics includes the code of ethics of the IMA regarding the relationship between medical practitioners and commercial companies (hereinafter: the "**IMA Code of Ethics**"), which is directed towards the medical community, and the marketing code of ethics of drug companies operating in Israel (hereinafter: the "**Code of Ethics**"). The Code of Ethics is based on the ethical rules of the IFPMA (the International Federation of Pharmaceutical Manufacturers Associations), adjusted to the conditions in place in the State of Israel, and includes ethical provisions regarding the advertising of medicinal products by drug companies. Any company operating in the field of medicine and wishing to adopt the Code of Ethics (even if it is not a member of the organisations that published the Code) may give notice of such in writing to the Joint Supervisory Committee, after which the provisions of the Code of Ethics will apply to it. Most of the large drug companies operating in Israel have accepted the provisions of the Code of Ethics. Additionally, some of the drug companies have internal codes of ethics which deal, among other things, with advertisement of medicinal products.

1.2 How is "advertising" defined?

Advertising is defined differently in each statute for the purposes of the statute in question. Thus, for instance, the Preparations Regulations define 'advertising' as: "the provision of information in writing, in the media or in any other manner". Whilst the Sale of Non-Prescription Preparations Regulations define 'advertising' as: "advertising orally, in writing, in print or in any other media which a person interested in marketing a non-prescription preparation does or which is done on behalf of such a person and directed at the public in whole or in part".

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?

Legislation in Israel does not require drug companies to make arrangements to comply with the provisions of laws and regulations regarding the advertising of medicinal preparations.

Under the Code of Ethics, a company that adopts the Code of Ethics is required to act to implement the Code among its employees. The

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company must set down procedures to ensure performance of all relevant local and international codes and must oversee all operations and advertisements intended to promote sales (section A.7. of the Code of Ethics); to ensure that all marketing and sales personnel are well-versed in the provisions of the laws, regulations, relevant procedures and the Code of Ethics, and act in accordance with them (section B.1. of the Code of Ethics); to provide medical representatives with an internal or external training course so as to give them sufficient scientific knowledge to enable them to provide full and precise information regarding the drug that they are promoting, and to obtain "medical representative" certificates for candidates who pass the requisite training courses (section B.2. of the Code of Ethics).

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 a medical preparation in the media, in non-scientific or professional journals or in any other way requires the consent of the Director General of the Ministry of Health, or a person acting on his behalf, prior to effecting the advertisement (section 28 of the Preparations Regulations; section 17(a)(1) of the Sale of Non-Prescription Preparations Regulations).

The Ministry of Health procedures regulates the submission of an application for approval of an advertisement, and provides that an application for an advertisement must be submitted on the application form attached to the procedure, and must contain four copies of the wording of the advertisement (including a visual representation if relevant), and the pamphlet to consumers with the date of the approval of the drug (section 3 of the Ministry of Health procedures). Advertisement applications are handled within 21 business days of the date of submission of the application. The Ministry of Health may approve or reject the application, or may require changes to be made to the wording of the advertisement. Where changes are required to be made to an advertisement application, the application will be deliberated once again within 14 business days of the date of receipt of the renewed application containing the amendments requested by the Ministry of Health. The approval of the advertisement is sent in the form attached to the procedures and is valid for one year. An application may be made for extension of approval of the advertisement on the form attached to the procedures. The application for extension of force of the approval will be handled within 5 business days.

In addition to the approval of the Ministry of Health, under the Second Television and Radio Authority (Prior Approval of Advertising Broadcasts) Rules, 5754-1994, the Director of the Second Television and Radio Authority may make orders regarding broadcasts or classes of broadcasts that require prior approval. Accordingly, in the case of radio advertisements for health, drugs or treatments on the radio channels of the Second Television and Radio Authority the franchisee must ensure that the advertising broadcast and the claims made in it are trustworthy, and must ensure that proper expression is given to the adverse effects that users might suffer. In addition, any health advertisement must include remarks by the Ministry of Health where such are required (Rule 11 of the Second Television and Radio (Ethics in Radio Broadcast Advertisements) Rules, 5759-1999). Such an advertisement on the television channels of the Second Authority requires that the broadcast franchisee obtain a medical opinion as to the trustworthiness of the broadcast, relevant remarks by the Ministry of Health, and the prior consent of a committee of medical experts on behalf of the Council of the Second Television and Radio Authority in the event that a proper evaluation of the broadcast requires medical expertise (Rules 42-43 of the Second Television and Radio Authority (Ethics in Television Advertisements) Rules, 5754-1994). Note that under the Second Television and Radio Authority Rules, the Ministry of Health's approval of an advertisement under the Preparations Regulations is not a necessary precondition for broadcasting the advertisement.

Radio advertisements on Israel Broadcasting Authority channels require the prior consent of the Director of the Broadcasting Authority. Advertisements for preparations or medicines that purport to cure various psychological diseases and deficiencies are prohibited unless the Ministry of Health's prior consent proving the efficacy and safety of use thereof is obtained (with the exception of drugs manufactured by a recognised manufacturer for the relief of headache, toothache, colds, etc., which do not require the prior consent of the Ministry of Health) (Rules 3 and 7(11) of the Broadcasting Authority (Radio Advertisements and Announcements) Rules, 5753-1993).

Television advertisements for medicinal preparations or medical treatments on a designated health channel require the approval of the Ministry of Health under section 28(b)(2) of the Preparations Regulations, and a medical opinion regarding the trustworthiness of the broadcast (Rule 60 of the Communications (Telecommunications and Broadcasts) (Advertisements, Service Announcements and Sponsorship Announcements in Designated Channel Broadcasts) Rules, 5764-2004).

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?

In the event that an advertisement for a medicinal preparation does not comply with the Sale of Non-Prescription Preparations Regulations and with the Ministry of Health procedures, the Ministry of Health may require the advertisers: (1) to amend the advertisement in the language and on the media in which it was advertised; (2) to publish a clarification approved by the Director General of the Ministry of Health or a person acting on his behalf, in three daily newspapers (one of which will be in the language in which the advertisement was made, one in Arabic and one in Hebrew) stating that the advertisement was misleading and incorrect; and (3) to prohibit advertising the preparation (section 22 of the Sale of Non-Prescription Preparations Regulations; section 3.7 of the Ministry of Health procedures). There is no designated process of appealing the decisions of the Ministry of Health with respect to the approval of an advertisement. However, the decision is subject to judicial review by an administrative petition before the District Court.

Where advertisement of a medicinal product does not comply with the general provisions of the Consumer Protection Law, the Director of the Consumer Protection Authority may order that the breach of the provisions of the Law cease (section 21(4) of the Consumer Protection Law) and may, with the consent of the Attorney General, order that an undertaking be given to avoid any act or omission or publication of notices in accordance with the Commissioner's decision (section 28 of the Consumer Protection Law), and may request that the court issue orders to prevent or to remedy the breach (section 30 of the Consumer Protection Law).

With respect to radio or television advertising broadcasts in deviation from the relevant rules and regulations, the Director of the Second Television and Radio Authority may disqualify a broadcast that does not comply with the rules or regulations, or may stipulate

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conditions for approval of such. This decision may be appealed before the Council of the Second Television and Radio Authority (Rules 3-4 of the Second Television and Radio Authority (Prior Approval of Advertising Broadcasts) Rules, 5754-1994). The Council for Cable and Satellite Broadcasts has similar powers, the Council's decision only being given after the broadcast licensee has been given an opportunity to make claims in the matter (Rule 60(b) of the Communications (Telecommunications and Broadcasts) (Advertisements, Service Announcements and Sponsorship Announcements on Designated Channel Broadcasts) Rules, 5764-2004). The Councils' decisions are subject to the judicial review of the Supreme Court sitting as the High Court of Justice.

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?

No penal sanctions have been set out in legislation made under the Pharmacists Ordinance beyond the prohibition of an advertisement or cancellation of approval for an advertisement. On the other hand, the Consumer Protection Law sets out penal sanctions of a monetary fine or a year's imprisonment.

There are also sanctions in the legislation against the broadcast franchisee (though not against the drug company) with respect to breach of the rules and regulations regarding the approvals required for television and radio advertisements.

Under the Code of Ethics, a Supervisory Committee under the Code of Ethics may impose sanctions against a company which breaches the Code or the instructions of the Supervisory Committee, including: reprimand, suspension of the right to use the ethics symbol and imposition of a monetary fine (section J.3.5.5. of the Code of Ethics).

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?

Enforcement by the Ministry of Health with respect to the advertising of medicinal products is partial only. In fact, the Ministry of Health only exercises its jurisdiction with respect to advertising initiated by the manufacturer of a medicinal preparation and not against media advertising that is part of journal articles. The rulings of the Supervisory Committee under the Code of Ethics regarding breaches of the Code of Ethics are open for public inspection and therefore, where the regulatory authorities are aware of such a breach which also constitutes breach of the relevant regulations and procedures, the authorities may exercise their jurisdiction as well. However, it should be noted that most of the issues regulated by the Code of Ethics are not set out in legislation. Furthermore, to the best of our knowledge, there is no connection between the enforcement actions under the Code of Ethics and the enforcement actions of the regulatory authorities, and to date, no regulatory enforcement proceedings have been instituted in light of the decisions of the Supervisory Committee.

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?

Claims can be made regarding unfair competition in the advertisements of drug companies on the grounds of harm to intellectual property, under the Commercial Torts Law, 5759-1999, or under the Unjust Enrichment Law, 5739-1979.

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?

Under the Pharmacists Ordinance, it is not possible to manufacture, market or order use of a preparation that has not been authorised in Israel. However, the Minister of Health may set down rules under which the Director General of the Ministry of Health may permit manufacture, marketing or use of an unauthorised preparation where such is required in order to provide vital treatment or for the purpose of research, provided that he is persuaded that such will not harm the public health (section 47A(b) of the Pharmacists Ordinance). The Preparations Regulations set out exceptions where, with the consent of the Director General of the Ministry of Health, a preparation that has not been authorised in Israel may be advertised in professional journals, in cases such as the following: a preparation intended for medicinal follow-up treatment, for medical or other scientific research, or a registered preparation that is intended for medicinal treatment other than in accordance with the conditions of registration (section 29 of the Preparations Regulations).

Note that drug companies are under an obligation to advertise in the professional literature, and this obligation arises where: a first registration certificate has been obtained for the drug or a first batch checking application has been submitted to the Institute, whichever is the later; a registration renewal certificate has been obtained for a drug in which the indication has been changed, or notice of authorisation of a change of indication in a registered drug has been obtained (section 28(c) of the Preparations Regulations).

Under the Code of Ethics, the prohibition against promoting the sale of a preparation that has not been authorised in Israel is not intended to harm the right of the scientific community or the public to be involved and properly updated as to scientific developments, it does not restrict the detailed and appropriate provision of scientific information relating to the medicinal preparation, including an appropriate analysis of the findings of studies, in the professional literature, at scientific conventions or even in the mass media (section A.6. of the Code of Ethics). Furthermore, promotional material may be provided at professional conventions and symposiums relating to preparations that are not registered in Israel, provided that such contains an appropriate declaration as to the stage of the registration process that the product is in Israel (section C.4. of the Code of Ethics).

A drug company may sponsor conventions and symposiums provided that the fact of provision of sponsorship is set out explicitly in advance and that provision of the sponsorship is not made conditional upon any undertaking by the recipient of the

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support to promote sale or indication of the medicinal preparation (section C.2. of the Code of Ethics of the Drug Companies). Furthermore, under the IMA Code of Ethics, the contents of conventions or symposiums are to be set by the scientific body only, and when presenting medical technology, doctors must provide a balanced picture and must review the variety of treatment possibilities.

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

Under the Code of Ethics, it is not possible to present or distribute promotional material to participants of conventions or symposiums for products that are not registered in any country at the time of the convention or symposium (section C.4. of the Code of Ethics). However, scientific documents regarding such preparations may be distributed, as set out in question 2.1 above (section A.6. of the Code of Ethics).

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 stated above, scientific information regarding unauthorised medicinal preparations may also be published for the public at large in the context of a press release, provided that such does not amount to sales promotion and that the advertisement was authorised by the Director General of the Ministry of Health (section 28(b)(2) of the Preparations Regulations). Under the Code of Ethics, publication of the information must be detailed and proper (section A.6. of the Code of Ethics).

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

Subject to compliance with the rules and regulations regarding publication of medicinal products, there are no provisions that prohibit the sending of scientific information to the medical community regarding preparations not authorised in Israel.

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?

Subject to the restrictions and requirements set out above, there are no provisions prohibiting the sending of scientific information to medical institutions regarding unauthorised drugs.

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?

Under the IMA Code of Ethics, doctors may not advertise the commercial products of drug companies. Likewise, under the IMA Code of Ethics, a scientific association or company may not participate in the advertising of a medical product not authorised for sale in the State of Israel.

3 Advertisements to Health Professionals

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

Advertisements of preparations in professional scientific journals must prominently set out the approved indication of the preparation, reference to the pamphlets to consumers and doctors accompanying the preparation (where required) and references to medical sources (section 28(b)(1) of the Preparations Regulations).

In addition, under the Code of Ethics of the Drug Companies, any advertisement aimed at promoting sales must contain the name of the preparation, the active ingredients, and the name and address of the manufacturer or agent responsible for marketing the preparation. Publication of detailed information to professionals must also include the characteristics and traits of use of the preparation, including principal indications and restrictions as recorded upon registration of the preparation, and details of how to contact the marketing company for the purpose of obtaining further information. If the publication relates to published studies, references for such studies must be set out expressly; any citation from medical literature or personal notices must also be quoted precisely in accordance with the intention of the author or the clinical researcher, in accordance with the meaning of the study (section E.2. of the Code of Ethics).

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?

An application for authorisation of a comparator advertisement regarding non-prescription preparations need not relate to "head-to-head" clinical trials, however, the party applying to make a comparator advertisement must persuade the Director of the Ministry of Health that a uniform basis of comparison was used, based on comparative scientific studies published in well-known professional journals, to show that one preparation is preferable to another (section 20 of the Sale of Non-Prescription Preparations Regulations). The Ministry of Health's procedures provide that the points of comparison are to be based on facts published in peer reviews in scientific journals.

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 Israel?

Comparator advertising is regulated by the Sale of Non-Prescription Preparations Regulations and by the procedures of the Ministry of Health which state that comparator advertising will only be permitted in the case of preparations that contain identical active ingredients, and after the Director General of the Ministry of Health has been persuaded (as set out in question 3.2 above) that one preparation is preferable to the other. Comparison of the preparations is not to be presented in any way that will give any artificial advantage to the preparation being advertised. In addition, the Director General of the Ministry of Health may authorise a comparison between the prices of non-prescription preparations where these contain identical ingredients, provided that the comparison does not slur or harm the competing preparation.

Where television advertisements contain comparisons between products, the franchisee must ensure that the products are similar and that the basis for comparison is uniform, that the points of comparison

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relate to facts that can be grounded and that the comparison is presented fairly, that the product compared is not presented in such a way as to create an artificial advantage to the product being advertised, and that no claim is made of general superiority of one product on the basis of a limited comparison (rule 26 of the Second Television and Radio Authority (Ethics in Television Advertisements) Rules, 5754-1994; rule 52 of the Communications (Telecommunications and Broadcasts) (Advertisements, Service Announcements and Sponsorship Announcements in Designated Channel Broadcasts) Rules, 5764-2004).

In addition, comparator advertising is subject to the general provisions set out in the legislation, the procedures and the Code of Ethics of the Drug Companies regarding correctness, precision and no misleading conduct in advertising.

Israeli law does not provide protection to a person using the trade mark of a competitor for the purpose of a comparator advertisement. However, in an *obiter dictum* the Supreme Court noted that in circumstances where the comparator advertisement reflects a desirable commercial practice which provides information to consumers, the court may consider providing common law protection to the comparator advertisement, provided that the information set out in the advertisement is correct and is not used in order to harm the rival product. Likewise, there is no restriction in Israeli law to a comparator advertisement that relates to a product that is unauthorised in Israel, subject to the approval of the Ministry of Health and the provisions of the rules and regulations referred to above.

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

Under the Code of Ethics, printed matter for the promotion of sales of a preparation, including scientific studies or the proceedings of congresses must contain precise, up-to-date and valid information, and the information must not create a misleading or erroneous impression. The scientific data that supports the traits ascribed to the preparation and the recommendations for use of it is to be available, upon request, to medical professionals (Chapter A of the Code of Ethics), and the material that relates to published studies must cite references explicitly. Likewise, citations from medical literature or from personal notices are to be made precisely in accordance with the intention of the author or the clinical researcher, and are to accord with the significance of the study (section E.3. of the Code of Ethics).

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 of medicinal products are not prohibited in Israeli law, provided that these comply with the regulations and procedures of the Ministry of Health, are approved by it, and contain all of the information required in advertisements of medicinal preparations (as set out in question 6.1 below).

According to the Code of Ethics, a brief promotional or "reminder" page may be distributed without including the full details required of an advertisement of preparations to doctors provided that such set out the authorised indications of the preparation, a recommendation to read the pamphlet to doctors, and a clear notification that further information may be obtained from the company (section E.2.2. of the Code of Ethics).

4 Gifts and Financial Incentives

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

Under the Code of Ethics, samples of medicinal preparations may be handed out to persons authorised to write out medical prescriptions in order to inform them of the existence of the preparation or to enable them to gain experience in using the medicinal preparation in the field of his employment, or upon request. Samples may not be handed out in commercial quantities. And in any event, the procedures of the medical institution at which the samples are handed out must be respected (section G of the Code of Ethics). The IMA Code of Ethics provides that a doctor may receive a number of packets of a drug that is usually and commonly given to doctors, marked with a label saying "doctor's sample only".

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

Under the Public Service (Gifts) Law, 5740-1979, employees of health funds and public hospitals are not permitted to receive any asset, service or benefit for no consideration from a manufacturer, importer or supplier of a medical preparation, apart from the exceptions set out in the Law (such as: a low-value gift given reasonably under the circumstances of the case).

Under the Code of Ethics, it is permissible to hand out promotional products for no consideration, the value of which is not substantial, provided that such are related to the service provided by medical professionals, or that will benefit patients (section D.2. of the Code of Ethics).

According to the IMA Code of Ethics, doctors may not receive gifts of cash or cash equivalents. However, a doctor may receive a gift of marginal value that is relevant to his job as a doctor, given as a gesture of politeness or for the purpose of providing information, such as: office supplies, signs, anatomical posters, etc., provided that receipt of the gift does not constitute consideration for prescribing a drug or giving a referral.

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 IMA Code of Ethics states that a gift of considerable value such as: a portable computer, digital camera, computer, valuable professional literature, etc. may only be received if the gift is given to a department or clinic or for the purpose of promoting scientific research and constitutes part of the department's registered inventory. Under the Code of Ethics, professional literature will only be granted to the libraries of hospitals or clinics in the community rather than directly to attendant doctors (section D.3. of the Code of Ethics).

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?

Under the Code of Ethics, it is not possible to give financial or

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material benefits to medical professionals in order to influence them to prescribe medicinal products (section D.1. of the Code of Ethics). The IMA Code of Ethics also prohibits doctors from receiving gifts, even if such are of marginal value, for prescribing drugs or making referrals for tests.

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 law in Israel regarding the advertising of medicinal products does not prohibit discounts from being given to medical institutions when purchasing drugs, provided that the discount does not constitute a prohibited gift under the laws and regulations set out above.

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?

Under the Sale of Non-Prescription Preparations Regulations, advertisements or promotion of the sale of a non-prescription preparation may not include a promise of a supplementary preparation or other product in consideration for purchase thereof. Likewise, use may not be made of a non-prescription preparation for the purpose of promoting the sale of other products (section 19 of the Sale of Non-Prescription Preparations Regulations).

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?

Neither Israeli law regarding the advertisement of medicinal preparations nor the codes of ethics prohibit giving refunds for faults in medicinal preparations.

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

Neither Israeli law regarding the advertisement of medicinal preparations nor the codes of ethics prohibit financing continuing medical education, provided that this is done in accordance with the relevant provisions of the statutes and regulations set out above.

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?

Offers of hospitality to health professionals is regulated under the Public Service (Gifts) Law, 5740-1979 (see question 4.2 above), and by a Circular of the Director General of the Ministry of Health dated November 16, 1998, regarding contracts with commercial companies (hereinafter: the "Circular of the Director General of the Ministry of Health") which sets out rules for contracts between medical institutions and commercial companies for the purpose of participating in conventions and seminars in Israel and overseas, financed by commercial entities.

Additionally, the IMA Code of Ethics deals with the participation of doctors in conferences funded by commercial companies and the way in which the doctor's participation is to be funded. Furthermore, the IMA has set up a forum to examine the connection between doctors and commercial companies which enables doctors to request and receive as comprehensive and clear a response as possible, in terms of law and ethics, on any question arising in this context.

The Code of Ethics deals with the ability of drug companies to offer medical professional hospitality expenses.

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?

Under the Code of Ethics, although it is not possible to give financial or material benefits to medical professionals in order to influence them to prescribe medicinal products, it is possible to offer hospitality at a reasonable level for the purpose of promoting sales (section D.1. of the Code of Ethics). During the course of conferences sponsored by a drug company, participants may be given entertainment programmes, hospitality and items that must be of a limited value and secondary to the primary purpose of the meeting. Payments in a reasonable sum to lecturers and speakers, and a refund of current expenses such as travel are acceptable. However, drug companies may not pay travel expenses for persons accompanying medical practitioners (section C.2. of the Code of Ethics).

A drug company may grant a study fund of a professional association or recognised medical institution a financial grant so as to enable or to ensure participation in seminars, continuing education and scientific conferences taking place in Israel or overseas. Likewise, a drug company may allocate sums to academic or scientific institutions, including the professional societies of the IMA which organise such conferences. In any event, a drug company may not offer direct assistance to members of the medical profession for the purpose of participating in a conference, but rather, only via the above entities (section C.3. of the Code of Ethics).

The Circular of the Director General of the Ministry of Health provides that employees of the Ministry of Health and the health funds may not receive direct assistance from a commercial company for the purpose of participating in a conference and that an employee may use research moneys or moneys available to the research fund of the institution at which he is employed in accordance with the by-laws of the fund and with its approval only.

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?

Since there is no statutory regulation of this issue in Israel, enforcement of hospitality arrangements at scientific conferences can be via the Supervisory Committee appointed under the Code of Ethics which is responsible for enforcement and implementation of the Code of Ethics.

The Supervisory Committee is comprised of five members, headed by a Judge Emeritus of the Supreme Court or a Judge Emeritus of the District Court. An application may be made to the Supervisory Committee for an opinion regarding matters relating to the Code of

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Ethics with respect to actions not yet taken by the applicant company, and a complaint may be made to the Supervisory Committee regarding breach of the provisions of the Code of Ethics. The Supervisory Committee has jurisdiction to impose sanctions such as reprimand, suspension of the right to use the ethics symbol and a monetary fine. The decisions of the Supervisory Committee are distributed to the organisations that are signatories to the Code of Ethics, and are open for public inspection.

Note that the Supervisory Committee's ruling will have an adverse publicity effect among medical professionals, which is greater than the monetary fine that can be imposed on the company.

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

As set out above (in question 5.2), lecturers and speakers at symposiums, conferences, etc., intended for the provision of information and accrued expertise in a given medical matter may receive payment in a reasonable sum, and a refund of current expenses such as: travel (section C.2. of the Code of Ethics).

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

Under the IMA Code of Ethics, it is not possible to pay and/or to promise indemnification to a doctor for keeping a record of clinical data. Keeping clinical data records may only be done by the association, scientific company or employer of the doctor, and with their knowledge. In this case, it is possible to obtain an undertaking from the financier to indemnify the association, scientific company, employer or persons acting on their behalf in the event of damages.

With respect to the participation by doctors in studies, the IMA Code of Ethics states that a doctor, association or scientific company may receive consideration for conducting a study provided that the remuneration is monetary, and is independent of the results of the study. The consideration for the study will be transferred to the researcher via the institution at which he is employed, or via the scientific association, and a grant for the study will be given to the researcher as a study grant or by way of allotment of medicines and/or medical equipment for the purpose of the study. In any event, the researcher must independently perform and publish the study, must not restrict himself by way of any agreement with the drug company to conduct the study and publish the results, and must take care to ensure maximum transparency in any publication of the study.

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

As a rule, under the IMA Code of Ethics, doctors cannot participate in the advertising of medicinal products. However, this depends on the nature of the specific market research and the marketing material provided in it.

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 medicinal preparations to the public subject to the following restrictions: the prior consent of the Director General of the Ministry of Health; the advertisement must be correct, clear, precise and must accord with the registered indications authorised in the certificate of registration of the preparation; the advertisement must include the name of the preparation, the names of the active ingredients of the preparation, referral to consultation with a doctor and to the pamphlet to consumers, the action of the preparation according to the approved indication; and contraindications and significant warnings (if any) in accordance with the discretion of the Ministry of Health.

An advertisement may not contain any declaration or data that are incorrect and/or that cannot be tested, or superlatives such as "the best", "the most efficient", "the only", etc. The advertisement must not mislead, scare or hint that the preparation has qualities or advantages that do not accord with the indication approved for it; and the advertisement may not encourage minors to take the preparation of their own accord (section 17 of the Sale of Non-Prescription Preparations Regulations). It is prohibited to advertise non-prescription preparations on television shows, over the internet, in newspapers or any other printed matter directed at minors, or to advertise on military installations, the Prisons Service or at schools (section 18 of the Sale of Non-Prescription Preparations Regulations).

Likewise, it is prohibited to advertise a non-prescription preparation by conducting lotteries, handing out samples of the preparation to patients or consumers, promising a supplement to the preparation or another product in return for purchase of it, or making use of the preparation in order to promote other products (section 19 of the Sale of Non-Prescription Preparations Regulations).

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

It is permissible to advertise prescription preparations with the approval of the Director General of the Ministry of Health (section 28(b)(2) of the Preparations Regulations). Under the Ministry of Health procedures, approval of advertising of prescription drugs will only be given in exceptional cases where it is important to distribute explanatory material that has added value to that in the pamphlet to consumers, on condition that the material is provided by the attendant doctor personally together with the prescription for the preparation, and is not distributed in pharmacies, clinics, doctors' waiting rooms, etc.

In addition, there is a prohibition against broadcasting advertisements on television for prescription drugs (rule 43(a)(1) of the Second Television and Radio Authority (Ethics in Television Advertisements) Rules; rule 61 of the Communications (Telecommunications and Broadcasts) (Advertisements, Service Announcements and Sponsorship Announcements on Designated Channel Broadcasts) Rules, 5764-1994).

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?

According to the Code of Ethics, campaigns may be conducted to increase awareness of diseases or to advance an area of specialty without noting the name of the medicinal preparation. In such a case, the public must be informed that the advertisement was financed by the drug company; furthermore, the campaign must take place at the highest level of precision possible in order to support the activities of medical service providers (section A.7. of the Code of Ethics).

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

The advertising of prescription drugs in non-scientific journals is subject to the approval of the Ministry of Health (section 28 of the Preparations Regulations) and under the Ministry of Health procedures, authorisation to advertise prescription drugs may only be given in exceptional cases, and in any event, not as part of an advertisement in non-scientific journals (see question 6.2 above).

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

There are no special provisions regarding advertisements made in the Company's brochures or annual reports. To the extent that the document in question is directed to the public or part thereof, the relevant rules relating to the advertising of medicinal preparations to the public at large will apply. Note that under the Code of Ethics, the restrictions that apply to the advertising of medicinal preparations were not intended to restrict the disclosure of information to the shareholder public and others regarding any medicinal preparation as required under any statute, procedures or regulations.

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?

Under section 40A of the National Health Law, 5754-1994, a registered owned, manufacturer or importer of a medicinal preparation must report to the Ministry of Health annually of any donation in cash or cash equivalents to entities active in the field of health and operating for no profit, including entities dealing in the representation of patients or in increasing awareness of matters in the field of health. Such reports are to be published on the Ministry of Health's website.

7 The Internet

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

Internet advertising, like all other advertising, is supervised by the Ministry of Health, and must comply with its instructions, and is also subject to the general statutory provisions applying to advertising. Note that under the Code of Ethics, the use of internet advertising is also subject to the code of conduct of the IFPMA.

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?

Where a company's website contains information regarding the health of patients, under the Protection of Privacy Law, 5741-1981, a person who has possession of a database that contains details of the health of persons is required to secure the information in the database (section 17 of the Protection of Privacy Law). The level of information security on the database and the supervision required of the permits to access the information are set out in the Protection of Privacy (Conditions of the Possession and Retention of Information and Procedures for Transfer of Information between Public Bodies) Regulations, 5746-1986.

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?

There are no rules or precedents in Israel law which apply to links to independent websites or reverse linking of independent websites.

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

Under the Code of Ethics, the internet may be used as a tool for providing precise and scientifically reliable information regarding drugs in a responsible manner, for the benefit of patients and in supreme recognition of the importance of maintaining their health. Therefore, any internet advertisement must set out the identity of the company and the target audience of the advertisement; the content of the information advertised must suit the target audience; the links must suit the target audience and its level of understanding; and information regarding specific countries must be provided in accordance with the requirements of each such country.

8 General - Medical Devices

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

There are no statutes, regulations or rules that apply specifically to the advertising of medical devices and therefore, the provisions of the general law regarding advertising applying to these kinds of advertisements.

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 statutes, regulations or rules that apply to promotion of medical devices and therefore, the restrictions on such activities shall be as set out in the provisions of general law (see question 5.1 above). However, it should be noted that the IMA Code of Ethics does not distinguish between receipt of consideration for promoting sales for drug companies and the receipt of consideration for promoting sales for medical device companies. Likewise, in the event that a medical device company accepts the Code of Ethics, the provisions of the Code of Ethics will apply to it even if it is not a member of the professional associations that have adopted and published the Code of Ethics.

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?

To the best of our knowledge, there was not significant development in relation to the rules relating to pharmaceutical advertising in the last year.

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

In recent years, we have seen an increased effort made to prohibit, via primary legislation, the receipt of remuneration by doctors from drug companies with respect to the prescription of drugs and the setting of restrictions on the financing of research and conferences. In this regard, a number of bills were tabled in the Knesset in recent years, but these did not advance in the legislation process. In the background, there is a dispute between the Ministry of Health, which is interested in promoting the new legislation, and the IMA which objects to it.

The IMA's position is that the proposed legislation will cause doctors to be disconnected from drug companies which will prevent the advancement of the level of medicine both academically and professionally. Therefore, in an attempt to stop the bills, a joint treaty was formulated between the IMA and the drug companies, which includes more appropriate ethical and social rules for handling the arrangement of the linkage between doctors and drug companies.

The statutory effort has been partially successful and is continuing. In 2006, section 4 of the Public Service (Gifts) Law, 5740-1979 was amended so as to apply expressly to employees of public hospitals and health funds with respect to gifts received from a manufacturer, importer or supplier of medical preparations.

Likewise, the Prohibition of Receipt of Remuneration from Entities Operating in the Field of Health Bill, 5769-2009 was tabled in the Knesset on April 1, 2009. The law is aimed at regulating the relationship between doctors and pharmacists on the one hand, and drug companies on the other.

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

In recent years, a practice of advertising prescription drugs via marketing campaigns to increase awareness of diseases, funded by drug companies, has started to develop. These campaigns do not mention the relevant brand of the drug company however, advertising broadcasts are often accompanied by dominant colours that are connected to prescription drugs.

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

The provisions of the Code of Ethics are based on the EFPMA rules, which have been adjusted to suit the situation in Israel. The Code of Ethics was published in October 2004, and since then has not been updated.

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