PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Sharon Gazit, Judy Amidor and Lennie Zivoni

GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The Israeli Ministry of Health (MOH) is the regulatory authority in Israel that oversees healthcare services.

The laws and rules that regulate the advertising of pharmaceuticals and medical devices are as follows:

- the Pharmacists Ordinance, 1981 (the 'Pharmacists Ordinance');
- the Medical Device Law, 2012;
- the Pharmacists' Regulations (Preparations), 1986;
- the Pharmacists' Regulations (Sale of Preparations Without a Prescription, outside a Pharmacy, or not by a Pharmacist), 2004;
- the Consumer Protection Law (1981) (the 'Consumer Protection Law');
- MOH Rule No 24/04 dated 15 March 2020, Advertising Preparations ('MOH Rule No 24/04');
- MOH Rule No 134 dated 2 November 2014 (last updated 2 March 2019) 'Raising Disease Awareness' ('MOH Rule No 134');
- MOH Rule No137 dated 5 January 2015 (last updated 1 August 2016) 'Rules for Improving the Use and Compliance with Prescribed Medicinal Treatment Using Non Commercial Information' ('MOH Rule No 137');
- MOH Rule No 49 dated 21 September 2003 (last updated March 2012) 'Distribution of Leaflets to Doctors/Consumers and Special Information on Preparations' ('MOH Rule No 49'); and
- MOH Rule No 13/2018 dated 22 October 2018 'Commercial Engagements by Medical Institutions' ('MOH Rule No 13/2018').

In addition, the Joint Ethics Covenant of the Israeli Medical Association and the Representative Organizations of the Pharmaceutical Companies Operating in Israel (published March 2014; the 'Joint Ethics Code') regulates, inter alia, pharmaceutical advertising.
There are also general rules that regulate advertisement activity made via television and radio under the Rules of the Second Authority for Television and Radio (placement of advertisements and commercial references in radio broadcastings), 1999.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

There is more than one definition of 'advertising', as manifested through different legislation and rules. The Pharmacists' Regulations (Preparations) 1986 define 'advertising' as 'providing information in writing, by means of communication or in any other way'.

The Pharmacists' Regulations (Sale of Preparations Without a Prescription, outside a Pharmacy, or Not by a Pharmacist), 2004 define 'advertisement' as 'publication, either through oral, written, printed or other means of communication, made by a person interested in marketing an over-the-counter preparation or made on his behalf and aimed at the public, in whole or in part'.

The Medical Device Law (2012) defines 'advertising' as 'publication either orally, in writing or in any other means, of medical equipment, which is publicly aimed, either wholly or in part, with the exception of publication in scientific literature'.

Israeli law does not differentiate between advertising and promotion. Promotion is one aspect of advertising that generally relates to short-term sales activity. In Israel, there is no specific legislation or directives that separately addresses this form of advertisement.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The regulatory authorities are mentioned in the response to Question 1.

The MOH oversees the regulation of device advertisements. In the event that an advertisement may lead

to harm or pose a risk to the public, the MOH has the authority to instruct the registration holder to stop sales of such a device, impose sale conditions or restrict the advertisement's type and form, as outlined in section 12 of the Medical Device Law, after conducting a hearing procedure.

Further, the MOH restricts pharmacists' involvement in promoting drugs and medical devices.

The Israeli Consumer Protection Law prohibits misleading advertisements.

The Physicians Ethics Code (published by the Israeli Medical Association) prohibits doctors from advertising in a way that causes excessive pressure on patients in clinics. Healthcare professionals employed at government healthcare facilities and organisations operating with an MOH licence are limited in their display of promotional materials in their offices, unless they have obtained prior authorisation.

As for the relationship between self-regulation and supervisory authorities, each health institution upholds internal policies that include self-regulation procedures. Often, such procedures may be stricter than enforcements performed by the MOH. From our experience in the industry, we find that self-regulation is primarily carried out by pharmaceutical companies, especially when dealing with physicians. Self-regulation seems to supplement legislation and guidelines issued by the MOH, and, if anything, adds clarity and stricter requirements on physicians because the pharmaceutical companies have been taking the lead to add contractual provisions to implement their own self-regulation.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

The MOH is responsible for approving the advertising of other regulated items, such as medical devices, food and cosmetics. When a product could be classified either as a medicinal product or medical device, the MOH refers to sections 9 and 10 of the Medical Device Regulations (2013). This involves assessing the product's primary function, and the expertise required for its use. The MOH typically aligns with the classification made by foreign regulatory authorities, especially if the product or similar ones have been categorised as either a device or medical product. In cases in which foreign regulatory bodies differ in their classification, the MOH generally adopts the classification assigned by the United States Food and Drug Administration (FDA).

MOH Rule No 024/04 states that, pharmaceuticals and/or medical devices that do not require a prescription, and are not classified as medicine, may be advertised, provided there is a clear notification stating whether each mentioned treatment is a drug, medical accessory, concoction, nutritional supplement and so on. The advertising of such non-medicinal products must comply with specific procedures and regulations set by the relevant authority within the MOH, such as the food service or the medical equipment department, which is responsible for the approval and oversight of the aforementioned types of products.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and, if so, which ones?

According to MOH Rule No 24/04, the advertisement of prescription pharmaceuticals together with non-prescription pharmaceuticals is not permitted. A general statement of a company's products cannot include both prescription pharmaceuticals together with non-prescription pharmaceuticals on the same page of a company's website, or in any other medium, and must always be on separate (web) pages.

Advertising prescription pharmaceuticals or providing information regarding prescription pharmaceuticals to the general public is prohibited.

Publishing non-prescription pharmaceuticals to the public must be carried out according to Regulation 28 of the Pharmacists' Regulations (Preparations) 1986 and Regulation 17 of the Pharmacists' Regulations (Sale of Preparations Without a Prescription, Outside a Pharmacy, or not by a Pharmacist) 2004, and only after written approval from the department of registration of pharmaceuticals is obtained.

Publishing non-prescription pharmaceuticals shall:

1. not be in a way that may be misleading or deceiving, or create tension or imply that the pharmaceutical will provide consumer benefits or advantages not in accordance with its labelling;
2. not encourage minors to use it;
3. be accurate and clear; and
4. include the following warnings: 'we advise consulting with a physician or a pharmacist prior to usage and to review the consumer leaflet' and 'contains active substance _____'.

The aforementioned obligations do not apply to publications made in a professional scientific magazine, or to an advertisement that only includes a picture of the pharmaceutical or its box (provided that it mentions the preparation's commercial name, its strength, usage, quantity and approved labelling, as well as the warnings set forth in 4 above).

According to MOH Rule No 24/04, the content of an advertisement for a non-prescription pharmaceutical shall include the following:

- pharmaceuticals' title;
- active ingredients (in an audio advertisement of pharmaceuticals containing over three ingredients, one can refer to the consumer's leaflet for a list of the active ingredients);
- a picture of the pharmaceutical (other than in an audio advertisement);
- a referral to the consumer's leaflet in the following form: 'prior to usage please review the consumer's leaflet';
- the approved labelling of the pharmaceutical; and
- additional information as required and according to the publishing of a non-prescription pharmaceutical committee, such as warning labels, age limit and duration of use.

Publications shall not include:

- information not supported by data submitted within the filing file of the pharmaceuticals;
- superlatives (eg, the best, the most efficient, the only one and the solution);
- misleading information;
- minor-designated publication for kids and teenagers up to 16 years old;
- information that may encourage uneducated use of the pharmaceutical; and
- benefits or information that may encourage overuse of the pharmaceutical, such as sample distribution, coupons, gifts, buy one get one free and reduced price for consumers.

Publications may include:

- the maximum consumer price of the pharmaceuticals;
- a clear and simple description of the pharmaceuticals' action;
- content addressing diseases and treatments;
- reference to the scope of sale of the pharmaceutical (eg, the bestselling) in accordance with actual sales data, international databases or local polls conducted independently by authorised organs without the involvement of the registration holder;
- in a visual medium advertisement (papers, billboards, ads, television, movies, social media etc), the active ingredients and the following: 'prior to usage please review the consumer's leaflet';
- in an audio publication (eg, radio), a clear list of the active ingredients and the following: 'prior to usage please review the consumer's leaflet';
- in a public conference/exhibit, the content must be submitted to the approval of the department of registration of pharmaceuticals, including content provided by pharmaceutical representatives; and
- no publication in military facilities, corrective facilities or schools.

With respect to special information addressed to patients, under MOH Rule No 49, in the event that the MOH has determined that patients must be specifically informed, it will determine the content of the notice, manner and place of publication, and shall instruct the registration holder to distribute the notice.
If the registration holder has decided to provide special information, the content of the notice shall be pre-approved by the MOH.

Special information designated for consumers shall also be published via the MOH website.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

MOH Rule No 24/04 addresses this form of advertising in section 5.4.1.4 by stating that advertising via visual media (eg, billboards, social media, mobile phone, websites and YouTube videos) is subject to detailing the active ingredients in the pharmaceutical and the inclusion of the following statement: 'one must review the consumer's leaflet before usage'. The statement must appear in a frame in big clear, readable black font, in a size no smaller than 14 point, in the language of the advertisement. The size of the frame must be equal to at least five per cent of the advertisement space, when the text is filling the greater part of the frame .

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

MOH Rule No 24/04 lays down the procedure for the approval of the advertisement of a non-prescription pharmaceutical.

An application for the approval of a non-prescription pharmaceutical shall be submitted by the authorised pharmacist of the pharmaceutical to the department of registration of preparations via a designated email address.

The application must include the following:

- a designated request form, the content of the requested advertisement (including with respect to an audio advertisement), as well as a visual presentation, if applicable;
- a request for advertisement via a specific website containing different contents, among which is information regarding a symptom, disease or suggestions for relief thereof, and reference to medical treatment and a specific pharmaceutical; all information regarding medical care and the pharmaceutical (which is not in the same language as appears in the consumer's leaflet) shall be marked in a clear and bold way, and such a request shall be accompanied by a declaration signed by the authorised pharmacist and the physician of the registration holder;
- an updated certificate of the pharmaceutical, including the relevant package size;
- a consumer's leaflet;
- the approved exterior package;
- an indication of the commencement date for marketing the pharmaceutical; and
- a request for an advertisement in a language other than in Hebrew shall be accompanied by an authorised Hebrew translation of all content.

Approval for an advertisement is effective for two years and may be extended for an additional period of two years.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

Section 29 of the Pharmaceutical Regulations specifically states that section 28(b) (2) applies to the off-label use of registered pharmaceuticals and/or devices. Section 28(b)(2) of the Pharmaceutical Regulations states that advertising the off-label use of pharmaceuticals and/or devices on media or in non-scientific or non-professional publications, or in any other way, is subject to authorisation from the MOH.
Advertising medicine or uses that have not received authorisation is not allowed.

Nonetheless, medical professionals, such as doctors, nurses and pharmacists, can receive updated information supported by professional literature, provided it does not conflict with the product's information leaflet. Such information shall not be used to promote usage not aligned with the drug's MOH registration. Distributing this information through a website is permissible only if access is restricted to medical professionals, as per section 3.1.2. of MOH Rule No 137. The medical literature cannot cover unapproved indications, and it should clearly mention the approved indications, referencing the product's patient or doctor information leaflet as outlined in section 28a.b of the Pharmacists Regulations (Preparations). However, information about a drug or an indication that is under a pending application for approval (and has not been approved yet) may be shared solely with medical staff in the stated ways, according to section 5.2.3 of MOH Rule No 24/04.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

The Pharmacists' Regulations (Sale of Preparations Without a Prescription, Outside a Pharmacy, or not by a Pharmacist) 2004 govern comparative advertisement under section 20(a) and determine that a comparative advertisement of non-prescription pharmaceuticals or pharmaceuticals containing identical active ingredients shall only be approved after the MOH is convinced that one pharmaceutical has preference over another, based on published comparative scientific research and after comparing the efficiency of the two pharmaceuticals on a unified comparison basis with comparable criteria.

The MOH may approve the price comparison of non-prescription pharmaceuticals containing identical active ingredients, provided that the comparison does not disparage or harm a competitor.

The use of trademarks or a brand name for comparison purposes is not formally regulated with respect to pharmaceuticals and would be a matter for the courts.

The Rules of the Second Authority for Television and Radio (Ethics in Television Advertisements), 1994 determine that comparative advertisement shall apply only to similar products and on a unified comparison basis. The comparative points shall be presented in a fair manner. The comparative product shall not be presented in a way that creates an artificial advantage to the advertised product.
An advertisement that claims general superiority of a product on a limited comparison basis is prohibited.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

Under the Israeli Patient's Rights Law, 1996, care providers include all of the following: physician, dentist, intern, nurse, midwife, psychologist, occupational therapist, physiotherapist, speech therapist, nutritionist-dietitian, clinical criminologist, podiatrist, surgical podiatrist, chiropractor and any other occupation that the MOH's director has recognised as a care provider.

The Physicians Ethics Code prohibits doctors from advertising in a manner that causes undue pressure on patients in clinics. Healthcare professionals that work at medical government institutions (which comprise most medical institutions), governmental clinics and private entities that act under an MOH licence and their employees are restricted in their ability to have promotional material in their offices, unless pre-authorised (MOH Rule 13-2018).

MOH Rule No 137 sets forth restrictions regarding information provided to healthcare professionals:

- the information must be updated and in accordance with the registration terms of a product and cannot contradict the physician's or consumer's leaflet;
- the public advertisement of non-registered pharmaceuticals or indications is prohibited;
- the information cannot be intended to influence or encourage a type of use that is not in accordance with the pharmaceutical's registration terms;
- providing information via a website is restricted to medical professionals registering and logging in with a password;
- registration holders may provide care providers who are not allowed to prescribe pharmaceuticals information necessary for their professional work by applying to the pharmacists department at the MOH for approval of the designated information and manner of presentation thereof; and
- it is prohibited to provide information of a specific pharmaceutical; however, information of the disease, potential treatments, potential side effects and others is allowed.

MOH Rule No 13/2018 clearly states that a health institution interested in allowing the activity of a pharmaceutical sales representative in its facilities must approve each representative as an 'authorised representative' in the institution. The activity performed by an authorised representative must be for the provision of professional information solely. It is prohibited to request an authorised representative for drug samples, medical food or supply. The receipt of samples for demonstration purposes solely must be pre-approved in writing. It is prohibited to receive any reward, incentive or personal benefit from an authorised representative, including travel expenses, office supplies, food and drinks.

MOH Rule No 49 sets forth provisions regarding the distribution of information of registered pharmaceuticals or any revision to the terms thereof. Information about a registered pharmaceutical (or any revision to its terms of registration) may be published in professional journals (including online journals) in a designated section thereof .

In addition, when a registration holder is interested in distributing special information to medical staff, prior approval of the notice (content, date of publication, manner and identity of recipients) must be obtained from the MOH.

In the event that the MOH determines that the distribution of the information is urgent and imperative, it will instruct the registration holder to distribute the information directly via a 'Dear Doctor Letter'.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

The definitions of 'advertisement' mentioned above in the response to Question 2 apply to all forms of advertising. The rules governing promotional (and advertising) activity apply equally to virtual and non-virtual advertising. There are no rules particularly governing the online advertisement of pharmaceuticals and medical devices.

The MOH issued a circular dated 26 May 2019 titled 'Standards for Operating Remote Health Services (Telemedicine, Tele-Health), which regulates the practice of telemedicine in Israel. Therefore, any form of online interaction with healthcare professionals may be subject to the provisions of the aforementioned circular .

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

The Physicians Ordinance [New Version] 1976 prohibits advertisements by physicians, directly and indirectly, which may be misleading or disrespectful of the profession.

The Physicians Regulations (Prohibited Advertisement), 2008 regulate advertising performed by physicians, in Israel and abroad, for licensed Israeli physicians. The regulations do not apply to an article or journalistic piece because they are not deemed advertisements.

The regulations stipulate that an advertisement for a physician shall be deemed misleading or offensive to the integrity of the profession ('misleading advertisement') if it includes the following:

- false or misleading facts;
- information about successful medical treatment (unless approved by the MOH);
- any guarantee of successful results of a medical treatment;
- superlatives regarding a physician's skills, knowledge or professional competence;
- mockery or defamation with respect to another physician or care provider;
- use of the title 'specialist', which was not approved in accordance with the Physicians Regulations (approval of specialist title and exams), 1973;
- names, pictures or images of celebrities or known figures;
- names, pictures, photos or images of patients, or people portrayed as patients or physicians, unless specifically stated that such figures are not real patients or physicians; and
- pictures, drawings or photos of private body parts;

or if:

- it is transmitted via telemarketing or through a sales agent;
- it is published in newspapers or magazines, manuscripts or phone guides (and the advertisement exceeds specific size requirements or appears more than once in the same publication); and
- it appears on billboards; in online ads on websites containing violence, pornography or illegal content; on minor-designated websites; in pop-up ads; or in spam.

There are additional restrictions to advertisements of physicians: for example, advertisements that include prices, special offers, awards or discounts are prohibited, as well as advertisements that include information about patients that may lead to the identification of such patients (even if the patient has given consent) or advertisements that encourage medical care through fear.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

As mentioned above in the response to Question 10, MOH Rule No 13/2018 clearly states that a health institution interested in allowing the activity of a pharmaceutical sales representative in its facilities must approve each such representative as an 'authorised representative' in the institution. The activity performed by an authorised representative must be for the provision of professional information solely. It is prohibited to request drug samples, medical food or supply from an authorised representative. The receipt of samples solely for demonstration purposes must be pre-approved in writing. It is prohibited to receive any reward, incentive or personal benefit from an authorised representative, including travel expenses, office supplies, food and drinks.

Under the Joint Ethics Code, samples provided to physicians must be clearly marked as samples that are 'not for sale'. It is also prohibited to provide samples in commercial quantities.

Under MOH Rule No 13/2018, healthcare professionals that work at medical institutions are not allowed to accept or request any gifts or incentives, or personal benefit of any kind (including conference-related travel expenses, office supplies, food or drinks).

According to section 50 of the Joint Ethics Code, doctors can only accept insignificant nominal gifts, and may use a gift if it is not personal and if it is intended to improve the level of the clinic/department, or to improve the quality of care and service to patients, provided, however, that the acceptance of the gift itself does not interfere with the professional independence of the physician and his/her colleagues or the clinic itself.

We also note that, to the extent that a physician is a civil servant, gifts in an amount greater than a nominal value given to such healthcare professional can violate the Civil Service (Gifts) Law (1979), and such a civil servant may be fined an amount of up to three times the value of the gift.

14. What rules govern the offering of hospitality to healthcare professionals?

Under MOH Rule No 13/2018, a health institution can receive financial assistance from an external body for the purposes of conducting conferences, educational activities and seminars in Israel (together 'conferences'), which are intended to provide scientific content other than marketing content. Such conferences shall not include activities that are not related to the conference's theme, such as entertainment or travel. In addition, accommodation expenses for conference days free of any professional activity cannot be covered by the organising company. Moreover, a health institution's employees shall not be rewarded or sponsored directly by an external body, including for travel expenses and after work activities. The aforementioned also applies to international conferences, provided, however, that an external body may allocate a general budget for a health institution to cover employees' travel expenses, subject to certain conditions set forth in section 12 of MOH Rule No 13/2018.

In addition, the Joint Ethics Code states that pharmaceutical companies are prohibited from hosting physicians in restaurants and other hospitality facilities at their expense, save for in the event that hospitality is modest and secondary to a lecture or any other significant professional content. This restriction also applies to the physicians' end, that is, they cannot agree to participate in such events subject to the above exceptions .

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

There is no clear definition of a donation as a promotional tool, but, by nature, it may raise concern as to conflicts of interests that such donations may create for recipient health institutions. Because donations made to health institutions raise concerns regarding a conflict of interest, under Israeli law, all donations in an annual amount exceeding NIS 2,500 must be reported to the MOH by both the donating party and receiving party. For further information, see the response to Question 19.
Under MOH Rule No 134, events funded through donations for the purpose of raising awareness of diseases shall clearly state the identity of the funding party and shall refrain from mentioning a specific pharmaceutical.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors

from the perspective of rules on the promotion of products?

Under MOH Rule No 13/2018 any activity of a pharmaceutical sales representative in a health institution is limited as follows (subject to prior approval and coordination with the health institution):

- Meetings or lectures or conferences or seminars for the institution's medical staff shall be conducted solely after the approval by the manager of the relevant institution.
- Personal meetings with pharmaceutical sales representatives are prohibited. However, meetings of three participants or more, among which, at least two participants are part of the institution's medical staff, are allowed. This restriction does not apply to personal meetings held with representatives of medical supply companies for the purpose of support or guidance regarding the use of medical supplies, provided such meetings do not include marketing or sales content.

In general, meetings of physicians and pharmaceutical sales representatives shall be coordinated in advance and in no event shall not be held at the expense of patient care working hours.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

The National Health Insurance Law, 1994, sets out a system of public funding for health services by means of a progressive health tax, administered by Bituah Leumi, or the National Insurance Institute, Israel's social security organisation, which transfers funding to health maintenance organisations (HMOs, sick funds) according to a formula based on the number of members in each fund, the age distribution of members and a number of other indices. There are four sick funds in Israel. Israeli citizens must join one of the funds, which provide healthcare under the Israeli national healthcare system.

HMOs also receive some direct government funding. The government provides HMOs with relatively wide discretion in determining how to spend their public funding, with the condition that HMOs must guarantee to provide the treatments set forth in the health basket as a minimum service to their members.

The national health basket includes a basic basket of drug technologies and services that should be made available to all Israeli citizens by HMOs. New drugs and devices may be approved and added to the national medical basket based on recommendations by a public committee on an annual basis. The additional budget for new drugs and devices is usually approved in advance and the committee decides which drugs or devices to recommend for inclusion.

The cost of drugs is negotiated by the MOH and, at times, HMOs. The committee's recommendations regarding new drugs and devices are based on the cost of treatment and other factors.

According to the Supervision of Prices of Goods and Services Law 1996, the Order Supervising Prices and Goods (Maximum Price of Prescription Medicines) 2001, and the Order Supervising Prices and Goods (Implementing the Law on Medicines) 2001, the maximum price of branded drugs without a generic competitor is determined by the average of the three lowest costs in Belgium, Hungary, France, the United Kingdom, Germany and the Netherlands. The price of a branded drug with a generic competitor or a generic drug is under the supervision of a governmental committee, and a petition needs to be filed to have the price raised.

Applications can be made to include registered drugs or drugs that have been submitted for registration and are likely to be approved during the year.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

We are not aware of any restrictions applicable to outsourcing advertising activities, other than the strict restriction of transferring advertisable messages through the services of the media, as set forth in MOH Rule No 137.

That being said, we emphasise that an advertisement must receive prior approval by the MOH (including with respect to its content) through an application form submitted by the authorised pharmacist.

Nevertheless, MOH Rule No 134, which regulates sponsored activities for raising public awareness to diseases, states that a third party (that is not the registration holder or related thereto) may engage with a registration holder for the purpose of conducting activity to raise awareness.

In addition, a health institution can accept financial assistance from an external body for the purposes of

conducting conferences, educational activities and others in Israel, which are intended to provide scientific content only and not marketing-related content. Engagements of that kind must be approved by the head manager of the health institution and are subject to the provisions of MOH Rule No 13/2018.

Research data remains confidential and cannot be obtained by third parties. The data can only be used by the MOH, without being supplied to a third party, after the expiration of the market exclusivity period to approve a generic formulation.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

Under the National Health Insurance Law, 1994, donations made to an organ in the health field, or to a physician or an investigator in the medical or health field, in an annual amount exceeding NIS 2,500 must be reported (by both the donating party and receiving party) to the MOH.

Donations are published publicly with the names of the donors and the health institutions, without mentioning the donation's amount.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Under the Consumer Protection Law, misleading advertisements are subject to one-year imprisonment or a fine of over NIS 200,000. The distribution of a non-approved advertisement is subject to fines and one year imprisonment under the Pharmacists Ordinance. Gifts in an amount greater than a nominal value given to healthcare professionals may be in violation of the Civil Service (Gifts) Law (1979), which imposes a fine on civil servants, in an amount of up to three times the value of the gift received.

As per section 5.8 of MOH Rule No 24/04, the MOH is responsible for demanding the removal of an advertisement and ordering the publication of clarifications with respect to such an advertisement. The MOH also has the authority to oversee the advertising of medical devices. In instances where an advertisement is found to be harmful or poses a risk of harm to the public, the MOH may enforce the registration holder to stop selling the device, condition the sale or impose restrictions on the types and methods of advertising, as established under section 12 of the Medical Device Law.

The MOH's Director General has the authority to impose a financial penalty, as outlined in section 60d of the Pharmacists Ordinance. Additionally, the joint forum, as defined under the Joint Ethics Code, has enforcement authority with respect to any activity and/or engagement by or between a physician or an association or scientific company and a pharmaceutical company.

Under a temporary article of the Pharmacists Ordinance, violators of the Pharmacists Regulations – Sale of Preparations Without a Prescription, Outside a Pharmacy, and Not by a Pharmacist are subject to up to six months in prison. Inducements can be handled under anti-bribery legislation. The punishment for bribing a public official is up to seven years of imprisonment, a fine of up to NIS 1m for individuals, a fine of up to NIS 2.2m for companies or four times the amount of the bribe, or a combination thereof. The MOH is authorised to impose financial sanctions, as well as criminal or disciplinary measures.

The Disciplinary Unit of the MOH handles disciplinary proceedings against medical and paramedical professionals. The deliberations of the disciplinary committees are public procedures (except for deliberations conducted pursuant to the Psychologists Law and the Medical Tourism Law, which are closed to the public), unless otherwise decided by the disciplinary committee. Decisions are published on the MOH website.

Following a review of a complaint submitted to the MOH by a relevant professional entity, a letter of complaint is submitted and a disciplinary committee is appointed. The committee examines the complaint in accordance with the relevant legislation and submits its recommendations regarding disciplinary measures as specified in the legislation, including a warning, reprimand, suspension or revocation of the licence.

Below is a list of legislation regulating disciplinary proceedings in court:

- Physicians Ordinance [New Version], 1976 (HE);
- Dentists Ordinance [New Version], 1979 (HE);

- Law Regulating the Practice of Medical Professions, 2008 (HE);
- Practice of Optometry Law, 1991 (HE);
- Pharmacists Ordinance [New Version], 1981 (HE);
- Psychologists Law, 1977 (HE);
- Medical Tourism Law, 2018 (HE);
- Hypnosis Practice Law, 1984 (HE);
- Midwives Ordinance, 1929 (HE);
- Public Health Regulations (Nursing Staff in Clinics), 1981 (HE);
- Dentists Regulations (Dental Hygienists), 1978 (HE); and
- Dentists Regulations (Definition and Regulation of the Field of Work of Dental Hygienists), 1986 (HE).

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

The MOH is the responsible regulator for the enforcement of regulations and directives in the field of pharmaceutical advertisement. Following a review of a complaint submitted to the MOH by a relevant professional entity, a letter of complaint is submitted, and a disciplinary committee is appointed. The committee examines the complaint in accordance with the relevant legislation and submits its recommendations regarding disciplinary measures as specified in the legislation, including a warning, reprimand, suspension or revocation of the licence.

Generally, a disciplinary committee consists of two professionals (one of whom is a representative of the relevant professional association) and an advocate. The role of the committee in some of the disciplinary proceedings is to hear the arguments of the parties, examine the evidence, prepare a factual basis and, finally, submit a recommendation to the Minister of Health (and, in some cases, the Director General of the MOH), who may accept or reject these recommendations. The powers of the minister have been delegated to a judge, and, currently, this role is filled by the Commissioner of Legal Decisions at the MOH, Judge (retired) Amnon Strashnov. As stated above in the response to Question 20, the joint forum under the Joint Ethics Code also has certain enforcement authorities. Competitors in the field of pharmaceuticals may seek relief from the competent courts in Israel in cases of alleged infringement.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

We do not expect any significant developments in the field of pharmaceutical or medical device promotion (advertising). However, in light of the increased use of artificial intelligence (AI) and digital media in the private and public sectors, we believe that privacy, data security and data integrity will continue to be enforced and audited, especially with respect to health data that is considered to be 'sensitive data' under the Israeli Protection of Privacy Law 5741-1981.

In general, the manner in which health data is used is not statutorily regulated, except for regulation in connection with the protection of data privacy (Protection of Privacy Law, 5741-1981 and Protection of Privacy Regulations (Data Security) 5777-2017). The MOH has issued circulars aimed at regulating the secondary use of health data, (MOH Circular regarding Secondary Uses of Health Data No 1/2018). We expect additional regulation as digital data and AI become more widely used in medical devices and health institutions.