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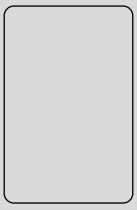

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Lexology Getting The Deal Through is delighted to publish the eleventh edition of Life Sciences, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Belgium and Israel.

Lexology Getting The Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.lexology.com/gtdt.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB, the contributing editor, for his continued assistance with this volume.

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Eran Bareket and Chen Ben Dori-Alkan
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ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

1 | How is healthcare in your jurisdiction organised?

In 1994, the Israeli government enacted the National Health Insurance Law. The main principle underlying the National Health Insurance Law is to ensure all Israeli residents without exclusions (such as for underprivileged or disabled populations) are entitled to health services.

According to the National Health Insurance Law, the state is responsible for funding a uniform healthcare basket of reasonable quality and accessibility (ie, within reasonable travel distance from the residence of the insured). Such services are provided by health insurance organisations – known in Israel as health funds.

The basket content is prescribed in the 1995 Order of Public Health Insurance (Basket Medicine) and is updated according to the changes made in the basket. The basket includes medical services and products (pharmaceuticals, medical devices, procedures, diagnosis and care, rehabilitation, hospitalisation, etc). In the framework of the determination of the state healthcare budget by the Israeli government, a Public Committee for Basket Expansion recommends on additions, changes and updates to the basket, within the limits of the budget allocated by the government. The Committee formulates its recommendations on the basis of professional and financial considerations as well cost-benefit analyses.

Following the National Health Insurance Law, all Israeli residents are insured by one of the four health funds per personal preference. The health funds are both the insurers and the providers of healthcare services and products included in the basket. Health funds may also subsidise services (in partial or in full) that are supplementary or in addition to the basket, for an additional payment, such as private physician consultation, private hospital surgeries or alternative medicine.

Israel's Ministry of Health (MoH) regulates healthcare in Israel. In addition to being entrusted with the assurance and quality of healthcare in Israel, it is also a healthcare service provider. The MoH operates around a dozen state hospitals as well as mental health hospitals and geriatric hospitals. Although health funds' primary function is to provide continual healthcare services, some health funds also operate several public hospitals.

One health fund operates the largest network of private hospitals and medical services in Israel.

Other public healthcare institutions and non-profit organisations exist that provide services to the MoH and the health funds, which may include primary care, for example, by Magen David Adom (the Israeli equivalent of the Red Cross).

Several private insurance companies also offer individual or group insurance. These companies do not provide healthcare services, which are received from private healthcare organisations and professionals.

Financing

2 | How is the healthcare system financed in the outpatient and inpatient sectors?

The public healthcare system in Israel is funded by the state healthcare budget and health insurance payments. Financing also includes several types of co-payments for certain services and medicinal products included in the basket.

Health insurance payments are collected by the National Insurance Institute from essentially all Israeli residents as a progressive tax from the salary of the insureds. This replaced the independently run health fund collection systems. Certain parts of the population are exempt from these payments, including children, inmates and soldiers (the army provides health services to soldiers in lieu of health funds).

The healthcare budget includes financing of the basket throughout, both inpatient and outpatient, whether falling under the responsibility of the MoH or the health funds.

The majority of the population also pay health funds for supplementary services not included in the basket. A growing amount of the population is also paying for private insurance, mostly related to outpatient services.

Basic structures

3 | What are the basic structures of the provision of care to patients in statutory and private care?

Most provision of care is provided by the health funds, which are statutorily organised. The rest is provided by private insurance, according to the different insurance policies (see question 1).

HEALTHCARE SERVICES

Authorisation

4 | What steps are necessary to authorise the provision of health services, and what law governs this?

The National Health Insurance Law governs the provision of health services (ie, the basket, for all Israeli residents).

For requesting provision of health services outside the scope of the basket (eg, off-label use), a petition to a special committee of the respective health fund must be submitted and its decision may be appealed to a regional labour court. See question 25.

Structure

5 | Which types of legal entities can offer healthcare services?

See question 1.

Health funds are non-profit organisations, some of which also operate public hospitals. Other public hospitals are mainly governmental entities or owned by associations. Private entities can also offer healthcare services (such as clinics and professionals).

Requirements for foreign health services providers

6 What further steps are necessary for foreign companies to offer health services?

The MoH regulates the (private and public) healthcare services offered in Israel.

In order to offer healthcare services in Israel, an entity has to comply with the relevant laws and regulations, set forth, inter alia, in the Public Health Care Ordinance of 1940, Public Health Regulations (Registration of Hospitals) of 1966 and Public Health Regulations (Registration of Clinics) of 1987.

Medical institutions – such as hospitals, surgical clinics and other specific clinics, such as dialysis clinic or oncology clinics – require a licence from the MoH in order to offer health services. Other clinics, such as private dentist clinics or private clinics that do not offer medical procedures, do not require a licence from the MoH.

The approval for establishment of a medical institution, the receipt of a licence, registration certificate and permit to operate, are issued if all requirements and conditions are met, according to the relevant and specific health service sought. The MoH also monitors the operation of medical institutions.

There seems to be no legal prevention for a foreign company to hold a health institution, as long as it is in compliance with the legal requirements, such as a medical manager in hospitals holding an Israeli licence to practise medicine in Israel.

ADVERTISING

Legislation

7 Which legislation governs advertising of medicinal products to healthcare professionals?

The 1981 Pharmacists Ordinance gives the MoH the authority to enact regulations relating the prohibitions and limitations of advertisement through any media of pharmacies, pharmaceuticals or other substances with medicinal effect and to determine the manner in which non-prescription drugs (NPDs) are to be advertised by an entity that is not a pharmacy or pharmacist.

Application for registration of a pharmaceutical

The relevant procedures for application are as follows. An application for the registration of a pharmaceutical is submitted to the registration unit of the MoH Pharmacy Department together with the requisite registration files. The applicant (and registration holder) must be an Israeli resident of a corporation registered in Israel. The application must be signed by a licensed pharmacist. The process includes the filing of an application as detailed in the MoH guidelines of 2015, titled 'Guidelines for filing applications for registration, change and renewal of pharmaceutical preparations'. These guidelines classify preparations into six different groups, which include preparations including an API, generic preparations and biosimilars. Each registration application, for each group, must contain certain files, as the guidelines specify. In general, an application may be composed of up to four main files, one of which includes bioequivalence data filed, for example, for an application to register generic preparations.

The application will be examined by the MoH's Pharmaceutical Administration Department and concurrently by the Institute of Medicine Review and Standards Institute (IMRSI) for the purpose of issuing a quality certificate. The application will subsequently be discussed by the appropriate committee according to the type of pharmaceutical. If a quality certificate has been received from the IMRSI and the application is found to be in order, the pharmaceutical will be approved for registration. A marketing approval is issued for five years and can be renewed for an additional 10-year period for each renewal. In addition to marketing approval, a permit to import a pharmaceutical into Israel issued by the MoH is required.

Validity of licences if medicinal products are not marketed within a certain time

According to the Pharmacists Regulations (Preparations), the MoH may condition registration of a preparation or to change or add to the conditions of a registered preparation to ensure the preparation's regular and continuous supply.

The same regulations state that a registration holder must provide the MoH notice of its intention not to renew the registration in the Israel Drug Registry and to indicate in this notice the reason for non-renewal of the registration and for termination of the preparation's marketing.

Marketing medicine without registration

According to the Pharmacists Ordinance, a pharmaceutical cannot be marketed in Israel unless it is registered in the Drug Registry. The Pharmacist Ordinance does, however, grant the MoH the authority to set forth rules whereby certain preparations may be manufactured or marketed without their registration or not per registration conditions (off-label use), if it is required, for example, for crucial treatment, research or export of the preparation, and only if the MoH is convinced it will not harm public health (section 47A(c) of the Ordinance).

According to Regulation 29 of the Pharmacists Regulation (Preparations), as amended in 2013, the MoH may allow certain pharmaceuticals to be imported, under certain circumstances, without their registration in the Israeli Drug Registry. These include, for example, preparations imported to (or outside of) Israel in an uncommercial amount and for personal use; preparations manufactured in Israel or imported into Israel for registration purposes; preparations intended for treatment of an epidemic; registered preparation for off-label use.

In 2016 the MoH published a notice concerning the specific conditions, documents and data required for a permit to import a pharmaceutical according to Regulation 29. The relevant forms and approvals, according to the specific circumstances of each application, are available online on the MoH website. MoH guideline No. 33 (issued in 2000, last amended in 2012) also concerns the import and marketing of drugs and pharmaceutical substances.

The Pharmacist Ordinance also allows the parallel import of a corresponding preparation, not by the registration holder, if the preparation is found to be identical to the registered preparation and is in compliance with storage and delivery conditions set forth in regulations and guidelines. All provisions relating to the registered preparation will apply to the corresponding preparation, mutandis mutandis, except for the actual registration requirement.

Regulations

Relevant regulations governing the advertisement of pharmaceuticals are the 1986 Pharmacists Regulations (Preparations) – namely, Regulation 28 – and the 2004 Pharmacists Regulations relating to the selling of NPDs by any entity other than a pharmacy or pharmacist (the NPD regulations).

Advertisement is defined in the Pharmacists Regulations (Preparations) as the act of providing information, in writing, via media or by any other means.

The following are some of the MoH guidelines:

- MoH Guideline (No. 24) titled 'The advertisement of pharmaceutical preparations according to Regulation 28' in 2000, last updated in May 2005 (MoH advertisement guidelines);

- MoH Guideline (No. 137) titled 'Rules for improved educated use and compliance to medical treatment of prescribed medicine, through non-commercial information' of 2015, as amended in 2016 (MoH Guideline 137); and
- MoH Guideline (No. 134) titled 'Raising diseases awareness – rules for accessibility of information to the public, funded by the registration owner directly or by third parties' of 2014, as amended in 2015 (MoH Guideline 134);
- an MoH circular, last updated in 2018, also governs the advertisement of medicinal products to healthcare professionals, setting rules for health institutions' engagements of a commercial nature (the 2018 MoH Circular); and
- the Rules of the Israeli Broadcast Authority (Commercials and Radio Notices) of 1993 as well as the Rules of the Second Authority for TV and Radio (Ethics in TV and Radio) of 1994 and 1999.

Main principles

8 What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

The Pharmacists Regulations (Preparations) prescribe, as a general rule, that preparations (including their package) must not be advertised in a manner contrary to the Israel Drug Registry and will only refer to its approved indications. Preparations are defined to include any type or form of substance used for disease treatment or prevention, for medical diagnosis, or given to cause, replace or amend a physiological function.

The Pharmacists Regulations (Preparations) further prescribed that the advertisement of a preparation in professional scientific articles must comply with certain restrictions, such as emphasised reference to the drug's indication.

MoH Guideline 137 also regulates information relating to prescription-only medicines (POMs) that can be distributed by the medicine registration owners (or any other party) to physicians, pharmacists and nurses. As a general rule, as prescribed in the guidelines, the advertisement of unregistered preparation or indications is prohibited, all in accordance with the Pharmacists Regulations (Preparations). The information will be available to said professionals, will include the consumer and physician leaflets and may also include information from professional literature.

The 2018 MoH Circular sets out rules on the advertisement of pharmaceuticals to healthcare professionals by medical pharmaceutical sales representatives. These include prohibition to receive any pharmaceutical or medical device sample (except a sample used to demonstrate the product, which must be MoH pre-approved), allowing only pre-approved materials to be distributed to health institutions, professionals or conferences organised by a health institution (excluding physician leaflets or peer-reviewed articles, which need to be presented to the MoH but not need pre-approval).

The Pharmacists Regulations (Preparations) prescribe that the MoH has the power to condition marketing of a preparation by demanding distribution of a physician's leaflet.

MoH Guideline No. 49 from 2003 concerns the distribution of labels to physicians and special information relating to pharmaceuticals, and specifies the requirements of a registration-holder for distributing leaflets.

Advertising of medical devices

9 Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

The 2018 MoH Circular also applies to the medical device sector.

The 2012 Medical Device Law has not yet taken effect (despite being enacted several years ago) since certain regulations have not yet been legislated. Thus, any regulations under this law are not yet in force.

Though not yet in effect, the Medical Device Law defines advertisement as any type of publication, excluding professional literature. Under the law, the MoH will have the power to determine, within the framework of a medical device registration, conditions and limitations relating to the manner and content of a medical device advertisement.

The Medical Device Law also states that if the MoH becomes aware of an advertisement of a medical device that is harmful or may harm public health, it is allowed to order the registration holder, the manufacturer of the medical device or the entity that markets it, to cease its manufacture, marketing or use, or otherwise impose restrictions on the entity responsible for the advertisement or demand a recall or any other order necessary for the protection of public health, subject to a hearing.

The Medical Device Law also prescribes that entities not complying with issued orders or restrictions placed with respect to a medical device advertisement will be subject to sanctions under criminal law.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

10 What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

In recent years, the MoH attempted to examine, evaluate and promote secondary uses in health data in order to develop the digitisation in the healthcare sector, including for the development of personalised medicine, preventive medicine, medical tools, etc. A special committee (and sub-committees) were established to discuss the implementation of secondary uses of health data. Their recommendations were published in 2018.

Consequently, the government has issued a decision (No. 3709) relating to the National Program for the Promotion of Digital Health and Leveraging the Advantages of Israel in Innovation, Medicine and Research. In this decision, it was decided that the Ministry of Health, after deliberation with the Ministry of Justice, will promote legislation for the implementation of the Committee's recommendation, including the purpose of use, protection of privacy, transparency and accessibility of data, etc.

Pending promulgation of such legislation, the MoH issued two circulars, published in January 2018, intended to promote secondary use of health data as well as for collaborations involving health data as well as set rules for said use or collaborations (Health Data Circulars).

Currently, the legislation in Israel regulates the protection of privacy in a general manner, including in the framework of the Privacy Protection Law of 1981 and additional regulations implementing the law. The Privacy Protection Regulations (Information Security) came into force in 2018 and apply to any database, public or private. These regulations define levels of security to which databases are to maintain. Databases containing health data, genetic data, biometric data and such must comply with certain specific, more restricted, requirements.

In October 2019, an exposure bill for the Patients' Rights Regulation (use of health data in research) was published. This handles the privacy and data protection of health data during research and collaborations.

Last, the field of medical devices is yet to be settled, thus, digital health in this field is yet to be elucidated.

Provision of digital health services

11 Which law regulates the provision of digital health services, and to what extent can such services be provided?

The Health Data Circulars currently prescribe the scope and extent of protection of health data. In general, unless otherwise specified by law or an explicit opt-in was determined for the use of personal identified or identifiable health data, any secondary use in said data will be under de-identification. Furthermore, any secondary use of health data for research purposes will be subject to the Helsinki committee approval.

The main rules are as follows:

- identified or identifiable health data will only be used for primary use (treatment), which will require explicit consent (opt-in);
- health data with no clear identification required for operational purposes, will require partial de-identification and explicit consent (opt-in);
- health data for the purpose of research must undergo full de-identification, which will not require consent other than specific cases specified by the Helsinki Committee (which will require opt-out); and
- use of data for statistical purposes, which undergo generalisation and de-identification, will not require consent.

In any event, additional limitations exist on entities outside the healthcare system, which cannot, for example, use the health data for commercial purposes.

In addition, the content and scope of Data Use Agreements (DUAs) was also prescribed in one of the circulars. The DUA will include in general provisions relating to the purpose of the use in the health data, the obligation not to use the data for inappropriate purposes and limitation on exclusivity, the obligation to secure privacy and information security and the duty to report to the ethical committee in case of a breach or if sanctions had to be imposed.

An additional circular of 2015 prescribes that medical institutions are to comply with International Organization for Standardization (ISO) standards relating to information security, which will be a condition for the renewal of MoH licences and will be examined in audits performed by the MoH.

Furthermore, a Circular of 26 May 2019 titled Standards for Telemedicine was published.

Authorities

12 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

In general, the Authority for Law, Technology and Information (responsible, inter alia, for the protection of privacy) is the entity responsible for regulating, monitoring and enforcing the Israeli privacy laws, including personal data in digital databases. In addition, as detailed above, the uses of health data and collaborations involving health data, are also regulated and monitored by the MoH.

Requirements

13 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

See questions 10 to 12. Under certain circumstances, specified in the Privacy Protection Law, and for certain entities (eg, hospitals and health funds) an information safety supervisor is to be appointed.

Common infringements

14 What are the most common data protection and privacy infringements committed by healthcare providers?

As previously mentioned, the legal regime in the matter data protection and privacy in the healthcare sector is yet to be formulated and legislated. We are not aware of any public information relating to specific infringements.

The State Comptroller has recently examined several aspects of privacy protection (March to August 2018). According to the report issued in 2019, most medical institutes do not comply with the ISO standards relating to information security. Furthermore, the MoH did not follow certain of the Committee's recommendations for the monitoring and enforcement of the rules of information security. It was also reported of cases in hospitals where the researcher received identified health data, contrary to the position of the MoH.

COLLABORATION

Legislation

15 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

There is no specific legislation governing relationships and collaborations between healthcare professionals and the pharmaceutical industry.

Section 4 of the 1979 Public Service Law (Presents), as amended in 2006, restricts the ability of staff of health funds and public hospitals to receive presents from, among others, a manufacturer, importer or provider of preparations or medical devices.

Section 40A of the National Health Insurance Law (enacted to promote transparency of financial collaborations involving entities of the health industry) states that a donor making donations to a health industry entity or physicians, pharmacists or researchers, above a certain amount, must provide the MoH annually with a list of the donations made during the preceding year and their details. A corresponding reporting duty is imposed on recipients of donations from health industry entities, including patient organisations. The MoH publishes these lists, including donations made to the MoH and their details.

The 2018 MoH Circular concerning the limitations applying to commercial engagements between the healthcare system and third parties significantly changed public healthcare practice between commercial bodies and the healthcare system.

This circular regulates engagement of a commercial nature between health institutions and external entities, which include:

- entities engaged in medical research or medical product manufacturing or marketing, which are not medical (MoH-licensed) institutions or government bodies; and
- commercial entities providing medical services.

The circular applies to all public and private health institutions licensed by the MoH, including their employees (both inpatient and outpatient) as well as hospital research funds, service providers and 'associations of friends', whether the activity is in Israel or abroad.

MoH Guidelines 134 and 137 also provide certain instructions relating to engagements between registration owners and healthcare professionals.

Collaboration with healthcare professionals

16 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

The 2018 MoH Circular states that any interaction with a medical or pharmaceutical sales representative must be in accordance with the Circular's provisions and pre-approved by the health institution. Such provisions include:

- each representative being authorised by the institution;
- prohibition on personal meetings with representatives;
- receipt of approvals for meetings, conferences and lectures of representatives to the staff of the institution; and
- meetings between physicians and representatives being scheduled in advance and not during time intended for patient treatment.

The same Circular states that a health institution employee may not request any type of benefit from the representative, including conference funding. A health institution may not request payments from an external entity, other than reasonable amounts for examining material distributed within the institution (or among its staff) or at a conference organised by the institution.

The institution may request any external entity where representatives are acting on its behalf to submit a monthly report regarding meetings conducted. This meetings report will be sent semi-annually to a special committee of the institution and will be published to the public.

MoH Guideline 137 provides additional specific rules, for example, in launching events of registered preparations and documenting instructional sessions conducted by the registration holder or any third party.

Collaboration with patient organisations

17 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There is no specific legislation governing the pharmaceutical industry collaborating with patient organisations.

The reporting requirement under the National Health Insurance Law also includes financial contributions to patient organisations.

According to MoH Guideline 137, relating to the collaboration between registration owners and patient organisations, the main rule is not to advertise POMs, to follow the relevant MoH guidelines, and not to encourage patients to seek a certain treatment from their physician. The patient organisations should maintain transparency and objectivity. Thus, for example, the patient organisation sponsored by the registration owner, may only use approved data published on the MoH website.

Common infringements

18 What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

The scope of infringements, if such exists, is unclear. Notably, the 2018 MoH Circular came into force rather recently (November 2018). Therefore, infringements relating to these provisions have yet to be seen.

Collaboration on medical devices

19 Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

The 2018 MoH Circular applies to the sector of medical devices as well as the pharmaceuticals sector, and thus are regulated in a similar manner.

COMPETITION LAW

Authority enforcement

20 Are infringements of competition law by healthcare providers pursued by national authorities?

The Israeli Competition Authority, established under the 1988 Economic Competition Law, oversees maintaining free competition in the market. The Competition Institute's activities include monitoring transactions, enforcement, consultation to governmental and legislative bodies and the like.

The Institute acts to ensure free competition is maintained, including actively monitoring the market, inspections, imposing financial penalties, and bringing legal action (through the Attorney General) in the case of violation of the Economic Competition Law.

Private enforcement

21 Is follow-on private antitrust litigation against healthcare providers possible?

Yes, private enforcement is available.

In recent years, actions (class actions and petitions to the Supreme Court) have been filed with respect to breach of competition laws by the pharmaceutical industry, especially with respect to pricing of pharmaceuticals.

Anti-corruption and transparency

22 What are the main anti-corruption and transparency rules applicable to healthcare providers?

There are no specific anti-corruption and transparency rules relating to healthcare providers, and the general laws apply (criminal law, companies' law, etc).

PRICING AND REIMBURSEMENT

Price regulation

23 To what extent is the market price of a medicinal product or medical device governed by law or regulation?

The prices of pharmaceuticals in Israel are subject to MoH control.

The prices of POMs are determined under the 1996 Law of Supervision of Prices of Consumer Goods and Services and the 2001 Order for Supervision of Prices of Consumers Goods and Services (Maximum Prices for POMs), as amended periodically, as well as the 2001 Order for Supervision of Prices of Consumer Goods and Services (Application of Law on Preparations).

The monitoring and pricing system of POMs is based on market prices prevailing in certain corresponding countries, from which a normative price is derived to reflect the retailer costs of the drug in these corresponding countries. Currently, as amended in 2018, the maximum price will be calculated as an average of the three lowest prices from seven corresponding countries (Belgium, Hungary, Spain, France, the United Kingdom, Germany and the Netherlands), or if there

is no corresponding price in three countries, an average of the relevant one or two countries, as the case may be.

Negotiations between manufacturers and providers

24 Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

Health funds are responsible for purchasing the majority of pharmaceuticals sold in Israel, thus enabling them to purchase off-patent pharmaceuticals at prices below the maximum prices set in the MoH pricing list.

Pharmaceutical manufacturers usually negotiate prices with the MoH as part of the decision process regarding additions to the basket. This is usually done through a hedging arrangement capping the state's expenditures during the first few years after introduction to the basket.

Reimbursement

25 In which circumstances will the national health insurance system reimburse the cost of medicines?

Health funds bear (with mostly nominal co-payments in certain circumstances) the cost of medicines within the basket.

In order to be funded for treatment outside the scope of the basket (also for off-label or compassionate purposes), a petition to a special committee of respective health fund must be submitted and its decision may be appealed to a regional labour court. Notably, in certain cases, these treatments may already be included in supplementary health fund service packages, which the majority of insureds hold.

Certain patients are entirely or partially exempt from co-payments, such as chronic patients who are exempt from paying for pharmaceuticals included in the basket above a certain limit.

Health funds have several reimbursement routes, for example, for insureds with financial needs or for certain services. In addition, a family cap for co-payments is set by health funds, and any overcollection of payment will be reimbursed upon request.

In consequence of a class action filed against a health fund, retroactive reimbursement also exists for holocaust survivors subsidised by the German government for their recognised health condition. The reimbursement is for medicine and treatment for the recognised health condition.

MoH Guideline No. 14, concerning conducting human clinical trials, as amended in 2016, states that patients who underwent clinical trials will continue to receive the research product – a pharmaceutical – for free for the following three years under certain conditions (the trials were successful, the product was registered for the requested indication, there is no concern of public health ramifications for the long term, and the like).

Price adjudication

26 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

Each health fund internally operates the pricing and reimbursability of medicinal products purchased for the health fund within the framework of the relevant laws and regulations.

A department at the MoH is responsible for planning, budgeting and pricing health services. It monitors and provides financial consultation to hospitals and health funds, coordinates pricing committees, conducts financial analyses, etc.

A Ministry of Finance pricing committee established under the 1998 Law of Supervision of Prices of Consumer Goods and Services provides its recommendation to the relevant ministers with respect to price monitoring. An administrative appeal is available.

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Discount

27 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

The manufacturers or distributors of medicinal products are statutorily only required not to exceed the maximum prices. In view of the pricing system, the possibility of parallel import and import of non-registered pharmaceuticals under Regulation 29, competitive prices are typically negotiated for off-patent drugs.

UPDATE AND TRENDS

Key developments of the past year

28 Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

See question 9 with respect to the Medical Device Law. See also question 10 for current and future legal developments regarding digitisation in the healthcare sector.

In view of the past year, there may also be initiatives for legislation relating to the vaccination of children and incentives relating thereto. There is currently no statutory obligation to vaccinate humans in Israel; however, section 19 of the 1940 Public Health Ordinance empowers the MoH under specific circumstances, such as an apparent epidemic, to take actions as it deems fit, to protect the population, including requiring vaccination in order to prevent epidemic. The MoH has exercised such authority very few times throughout the country's history.

Also, the MoH took measures to facilitate the general public's access to information about NDPs (see MoH Guideline 134). In addition, the MoH launched a mobile app from which the consumer may obtain information about a certain NPD by scanning its barcode.

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