

Israel

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REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities.

Regulation of pharmaceutical preparations (Preparations) is governed, among other things, by:

- The Pharmacists Ordinance (New Version) 1981 (Pharmacists Ordinance).
- The Pharmacists Regulations (Preparations) 1986 (Pharmacists Regulations).
- Other associated regulations enacted under them, and numerous guidelines issued by the Ministry of Health (MOH).

The Pharmaceutical Administration within the MOH (Administration) (*see box, The regulatory authorities*) is the regulatory body responsible for, among other things, the regulation of all pharmaceuticals in Israel.

The Institute for Standardisation and Control of Pharmaceuticals within the Administration (Standardisation Institute) supervises the quality of Preparations, by performing laboratory testing, carrying out inspections of manufacturers and evaluating data relating to the quality of Preparations for which registration is sought.

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

The National Health Insurance Law 1995 (NHI Law) guarantees medical insurance for every Israeli citizen or legal resident by one of the four Health Maintenance Organisations (HMOs).

The scope of the basic package of medical services that HMOs are required to provide (Health Package) is determined by law and updated annually.

HMOs are mainly funded by a progressive, income-based health tax, which is distributed between them on a capitation basis, according to the number and age of their insured members. Additional funding is received from the MOH's budget and from paid complementary medical services and health insurance packages provided by the HMOs.

3. In what circumstances are the prices of medicinal products regulated?

Maximum prices of prescription Preparations are regulated by the Comptroller of Prices at the MOH (Comptroller).

Changes in prices of non-prescription Preparations (OTC) are subject to the Comptroller's approval.

Changes in prices of non-prescription Preparations for general sale (GSL) should be reported to the Comptroller.

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

The National Health Insurance Order (Medication in the Health Package) 1995 lists the Preparations included in the Health Package and subsidised by the HMOs.

Each HMO has a slightly different subsidisation plan, which must conform with guidelines as specified in the NHI Law, and be approved by the MOH.

For most Preparations included in the Health Package, the patient's contribution amounts to 10% to 15% of the maximum retail price. Specific sectors enjoy further subsidies.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- To which authority must the application be made?
- What conditions must be met to obtain authorisation?
- Are there specific restrictions on foreign applicants?
- What are the key stages and timing?
- What fee must be paid?
- How long does authorisation last and what is the renewal procedure?

The authorisations required to manufacture a Preparation in Israel are:

- Manufacturing Approval under the Pharmacists Regulations (Good Manufacturing Practice (GMP) for Preparations) 1986 (GMP Regulations).
- Registration of the Preparation(s) in the Registry of Preparations (Registry) (*see Question 8*).

Application

An application for Manufacturing Approval is made to the GMP Supervision Department within the Administration.

The application should be accompanied with information concerning production facilities, control of manufacturing operations and capability of relevant personnel.

Conditions

The basic requirements for obtaining Manufacturing Approval are:

- Valid businesses permit (if required under the Business Licensing Law 1968).
- Compliance with the GMP Regulations.
- Appropriate qualifications of the managing personnel.
- Manufacturing complies with GMP according to the relevant EU directives.
- Inspection of the business by the Administration.
- The APIs used are manufactured under GMP conditions.

Restrictions on foreign applicants

The GMP Regulations do not contain restrictions specific to foreign applicants.

Key stages and timing

Under the GMP Regulations, a decision on an application for Manufacturing Approval or renewal of it is given within 120 days from filing (excluding waiting time for applicant's response, if applicable).

Any facilities' expansion or other material change should be approved by the Administration in advance, and a decision in relation to such approval is made within 90 days from the date of filing.

Fee

The current fee for seeking Manufacturing Approval is NIS35,000 (about US\$9,300).

Period of authorisation and renewals

The approval is valid for five years, and can be renewed for further periods of five years each.

An application for renewal must be filed no later than 120 days before the approval expires.

6. What powers does the regulator have to:

- Monitor compliance with manufacturing authorisations?
- Impose penalties for a breach of a manufacturing authorisation?

The MOH can prohibit production, importation or marketing, or cancel or not renew a Preparation's registration, if it becomes evident that the Preparation either:

- Harms or might harm general health or is unsuitable or ineffective for the prescribed indication.
- Is manufactured, imported and marketed contrary to the registration terms.

Breach of the Pharmacists Ordinance and its associated regulations is a criminal offence. The penalties for this range from fines and confiscation of production means, to up to six months' imprisonment.

To monitor compliance with the GMP Regulations, the MOH can:

- Enter any place where Preparations or raw materials are maintained and perform inspections.
- Demand details and documents.
- Take samples.
- Confiscate and/or destroy Preparations or raw materials and prohibit their sale or manufacture, if there is a concern that they harm or might harm public health.

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- Which legislation and regulatory authorities regulate clinical trials?
- What authorisations are required and how is authorisation obtained?
- What consent is required from trial subjects and how must it be obtained?
- What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?
- What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?

Legislation

Clinical Trials are governed by the Public Health Regulations (Clinical Trials in Human Subjects) 1980 and the relevant MOH guidelines, particularly, Guidelines for Clinical Trials in Human Subjects, 2006 (CT Guidelines). For the English version, see www.health.gov.il/Download/pages/GuidelinesClinical_Trials_Human_English.pdf.

The Clinical Trials Department at the Administration (CT Department) is the regulatory authority supervising clinical trials.

Authorisations

Clinical trials require authorisation from the following:

- The Ethics Committee at the medical institution where the trial is to be conducted (Institution).
- Director of the Institution.
- CT Department (not required for special clinical trials, as defined in the CT Guidelines).

- The Committee for Approval of Contracts with Commercial Companies (Commercial Contracts Committee) (applicable to most medical institutions).

An application for authorisation is filed by the chief investigator with the Institution's Ethics Committee. It must be accompanied by:

- The trial protocol.
- Informed consent forms.
- Investigator's brochure.
- Participants' enrolment notice.
- Letter to the attending HMO physician.
- A checklist.
- A sponsor's declaration, concerning the completeness and accuracy of the application documents and sponsor's undertaking.

Informed consent

A trial-specific form (based on the template enclosed with the CT Guidelines) must be signed by both the participant and the investigator, after the participant receives an appropriate verbal explanation concerning the trial by the investigator. A copy of the signed form must be delivered to the participant.

Obtaining the consent of minors or other legally incapable participants is subject to further restrictions.

Other conditions

The sponsor must sign an undertaking (*Appendix 4, CT Guidelines*), containing the following undertakings:

- To act according to the relevant local and international guidelines.
- To maintain appropriate insurance against third-party claims, covering also the Institution, its staff and the investigator.
- To provide the investigational Preparation free-of-charge throughout the period of the trial and, in certain circumstances, also post-trial supply for up to three years following its conclusion.
- To bear all the costs of the trial.
- Certain undertakings relating to publication of the trial's results.

Procedural requirements

The CT Guidelines include detailed provisions concerning, among other things, the:

- Supply, labelling and importation of the investigational Preparation.
- Reporting duties.
- Monitoring, maintenance of documents.

In matters not covered by the MOH guidelines, international guidelines (in particular ICH-GCP E6) apply.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

Registration of a Preparation in the Registry is a pre-condition for marketing, as well as manufacturing or prescribing it. Specific exceptions to the registration duty, which are subject to the Administration's approval, are listed in the Pharmacists Regulations.

Application

Application should be made to the Registration Department within the Administration.

Conditions

The basic requirements are:

- Marketing authorisation from a Recognised Country (see *Question 10*).
- Standardisation Institute certificate confirming the adequate quality of the Preparation.
- Evidence of safety.
- Evidence as to efficacy.
- The commercial name of the Preparation is not misleading.
- Evidence of GMP.

Restrictions on foreign applicants

An application can only be filed on behalf of an Israeli citizen or corporate body, and only by a responsible pharmacist possessing an appropriate permit. For this reason, most foreign Preparation manufacturers operate through an Israeli subsidiary and employ a responsible pharmacist (who may be a freelancer), or appoint a local importer to act as their agent, for registration purposes.

Key stages and timing

Under MOH guidelines, registration of a new Preparation should be completed within 360 days (all timeframes specified in MOH guidelines exclude waiting time for applicant's replies).

Following registration, the applicant must submit a first batch of the Preparation, its packaging and the final version of the consumer and prescription information for inspection before marketing it. Marketing is subject to each batch of the Preparation being inspected in advance by the Standardisation Institute or by a recognised laboratory, as applicable.

Fee

The following fees apply:

- Registration of a single Preparation: NIS5,599 (about US\$1,500).

- Standardisation Institute certificate: NIS3,072 (about US\$800) for an imported Preparation, NIS2,294 (about US\$600) for a locally manufactured Preparation.
- Batch quality test for registration renewal: NIS1,209 (about US\$320).
- Renewal fee: NIS1,119 (about US\$300).

Period of authorisation and renewals

Registration is valid for five years, after which the authorisation can be renewed for further periods of five years each.

If the registration is not renewed, the marketing of existing stocks of Preparations can continue for up to one year following expiration (unless the MOH directs otherwise).

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- Which medicinal products can benefit from the abridged procedure (for example, generics)?
- What conditions must be met?
- What procedure applies and what information can the applicant rely on?

An applicant seeking to register a generic Preparation is exempted from providing evidence of safety and efficacy, provided that bioequivalence and quality are established.

An abridged registration procedure is available for generic Preparations which already possess marketing authorisations from the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA). If no objection is made by the MOH, the registration procedure for these Preparations will be completed within 70 days.

Under the Administration guidelines, the registration procedure of a new dosage for an already registered Preparation will be completed within 180 days (excluding waiting time for the applicant's response, and provided that the original file meets the standards applicable on the date of submission and is identical to the submitted file, subject to necessary modifications). Preparations newly included in the Health Package enjoy preferential treatment as far as waiting time for examination is concerned.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

There is no recognition of foreign marketing authorisations as such. However, the Administration only accepts applications for registration of Preparations that already possess marketing authorisations from any of the following countries, and are actually marketed in them (Recognised Countries):

- The US.
- Canada.
- Any EU member state that joined the EU before May 2004.
- Switzerland, Norway, Iceland, Australia, New Zealand and Japan.

11. What powers does the regulator have to:

- Monitor compliance with marketing authorisations?
- Impose penalties for a breach of a marketing authorisation?

See *Question 6*. The MOH can also request the registration owner to provide it with additional data relating to the Preparation at any time.

12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Parallel imports of a matching Preparation (as defined in the Pharmacists Ordinance) are allowed, subject to the approval of the Parallel Import Department within the Administration, and under the following conditions:

- The Preparation being imported must have the same manufacturer as the Preparation registered in Israel.
- The Preparation is purchased directly from an authorised wholesaler in a Recognised Country or from a manufacturing site in a Recognised Country.
- The importer is a recognised medical institution or a Preparation wholesaler that maintains proper storage conditions, and can prove proper storage conditions during the entire supply chain.
- Submission of a manufacturer's detailed analysis certificate for the imported batch.
- Submission of a sample of the Preparation and its package, as marketed in the country of origin.
- Inclusion of a consumer information leaflet conforming to the relevant legal provisions.
- If the matching Preparation was not manufactured at the same site as the registered Preparation, certain additional evidence is required.

A Supreme Court decision from 2001 (*H CJ 5379/00 Bristol-Myers Squibb Company et al v Minister of Health et al, PD 55(4) 447*), relating to parallel imports of Preparations, focused on regulatory aspects. It left the question of the possibility of using intellectual property rights to oppose parallel imports undecided.

13. Please briefly outline the restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners.

Accepting grants or funding for research activities and medical conferences must be approved by the Commercial Contracts Committee (*MOH guidelines*).

State-employed medical practitioners are prohibited from accepting any benefit associated with their public position (save for specific exceptions), under rules applicable to state employees. Under the Public Service Law (Gifts) 1979, a gift accepted by a state-employee becomes the property of the state (save for specific exceptions, including a token gift, according to applicable custom).

Medical practitioners, healthcare institutions and Preparations' manufacturers are also bound by a voluntary ethics treaty signed in 2004 between their representatives. This treaty forbids, among other things, receipt by a physician of:

- Any reward of any value for prescribing a particular medicine or for recommending the use of certain medical technology.
- Preparations on a commercial scale.
- A monetary gift or equivalent (except for a gift of nominal value, relevant to the physician's work and given as a courtesy gesture or for receiving information, and is not a reward for prescribing a particular medicine or recommending certain medical technology). A valuable gift can only be given to a medical institution, to promote scientific research.

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

Under MOH guidelines, only a licensed pharmacy can market OTC Preparations over the internet, subject to both:

- The approval of a district pharmacist.
- Specific conditions in the guidelines (including separate display of each Preparation, display of the package and the consumer information leaflet, and publication of notices).

Prescription Preparations can only be issued on an original prescription being presented to the pharmacy, or an online prescription complying with the Electronic Signature Law 2001. Prescriptions can be transmitted by fax or other electronic means, provided that supply of the Preparation is only done against the original prescription. Subject to MOH approval, prescription Preparations can be distributed by a licensed pharmacy through a messenger, provided that the prescription Preparations are only delivered to the patient by the messenger against the original prescription.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
- What types of medicinal product cannot be advertised?
- What restrictions apply to advertising that is allowed?

Prior approval of the MOH is required for advertising Preparations in non-medical professional publications.

Both the Pharmacists Regulations and MOH guidelines contain specific provisions concerning the advertising of Preparations.

Generally, advertising prescription Preparations to the general public is prohibited.

Advertising non-prescription Preparations to the general public:

- Is subject to MOH approval.
- Must be true and clear.

- Must accord with the approved indication and be worded in accordance with MOH rules, as specified in its guidelines.

Additional provisions relating to advertising non-prescription Preparations (GSL) can be found in the Pharmacists Regulations (Sale of a Non-Prescription Preparation Outside a Pharmacy or Not Through a Pharmacist) 2004 (Regulations), and include, among other things:

- Prohibition of advertising mainly directed to children under the age 16, as well as advertising in schools, military facilities or jails.
- Limitations on sales promotion.
- Warnings to be included in the advert (including size of lettering).
- Conditions for approval of comparative adverts.

Under the Regulations, the following adverts do not require MOH prior approval:

- An advert containing only a picture of the non-prescription Preparation or its packaging, together with the Preparation's details and required warnings.
- Advertising a registered Preparation in professional publications (which is mandatory in certain circumstances, for example, on registration).

Broadcasting bodies are also bound by rules for advertising Preparations, which may impose stricter conditions than those imposed by the above legislation and guidelines.

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
- What information must the packaging and/or labelling contain?
- What other conditions must be met (for example, information being stated in the language of your jurisdiction)?

A Preparation's packing and labelling is governed by the Pharmacists Regulations and regulated by the Administration.

The packaging of the Preparation, consumer information (in Hebrew, English and Arabic, and for GSL Preparations also in Russian) and prescription information (can be in English) must be submitted for approval by the Administration.

Consumer information must include basic information about the Preparation, in simple language and printed clearly, such as:

- Storage conditions.
- Expiry date.
- Potential side effects.
- Recommended dosage.

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

The Pharmacists Regulations (Conditions for Opening and Operating of Pharmacies and Medicine Rooms) 1982 empower the Administration to regulate the marketing of traditional herbal medicinal products and homeopathic products. The regulation of these products focuses on their safety, while their efficacy is neither tested nor guaranteed by the MOH.

The Department of Medicinal Herbs and Homeopathy within the Administration maintains a list of medical herbs which, for safety reasons, can only be marketed by a pharmacist, and of other herbs that are generally prohibited for sale.

The manufacture and marketing of homeopathic products are regulated by guidelines published by the Administration.

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?

Under the Patents Law 1967 (Patents Law), patents are granted for inventions, whether products or processes, in any technological field which are:

- Novel.
- Useful.
- Non-obvious.
- Susceptible to industrial use.

Therefore, Preparations, related substances and processes can generally be protected by patents.

Patents are not granted for, among other things, methods of therapeutic treatment of the human body.

Applicable secondary legislation includes the:

- Patent Regulations (Office Practice, Rules of Procedure, Documents and Fees) 1968 (Patent Regulations).
- Patent Regulations (Extension of Period of Protection: Procedure for Application for Order, Opposition to Order, Application to Annul) 1998.

19. How is a patent obtained? In particular:

- To which authority must the application be made?
- What fee must be paid?
- What are the key stages and timing?

The authority

Applications are filed with the Patent Authority (www.justice.gov.il/MOJEng/RashamPatentim).

Fee

These are:

- Filing fee and publication of filing details fee: NIS1,164 (about US\$310). Under an amendment to the Patent Regulations from 1 December 2009 (which has not yet been published in the official gazette), an additional fee of NIS500 (about US\$133) per claim will be due for any additional claim, as from the 51st claim. Such amendment will come into force on 30 days from the date of publication.
- Second publication fee (on acceptance): NIS511 (about US\$135).

Process and timing

The key stages and timetable are as follows:

- Filing a patent application.
- Within few months from filing, preliminary examination of completeness and form of documents, and consequently publication of the filing details in the Patents and Designs Journal.
- Substantive examination commences a few years (two and a half to four and a half years) after filing.
- On acceptance, an abstract of the application is published in the Patents and Designs Journal. The application file is open for public inspection and filing of oppositions.
- If no opposition is filed within three months of the second publication date, a patent is granted.

Abbreviated examination may be available in certain circumstances, based on an international examination report according to a Patent Cooperation Treaty 1994 (PCT) application, or a granted corresponding patent or patent application accepted by an examining authority, such as the European Patent Office or the US Patent Office.

Immediate substantive examination can be requested where the circumstances justify it (for example, unauthorised exploitation of the invention claimed in the application).

20. How long does patent protection last? How is a patent renewed or patent protection extended?

Protection lasts for 20 years from the date of filing the application (subject to timely payment of renewal fees).

Supplementary protection for an additional term not exceeding five years may be available for Preparations and medical devices, subject to specific conditions. An extension order can only be granted for basic patents and, on request of the holder of the basic patent or exclusive licence, is filed within 90 days following registration of the relevant Preparation/medical device by the MOH (this deadline may be extended, in limited circumstances).

21. In what circumstances can a patent be revoked?

A patent can be revoked in revocation proceedings before the Patent Authority, or in infringement proceedings before a court. A patent is revoked if there are grounds on which it was possible to oppose granting the patent, including:

- The invention is not patentable (see Question 18).
- Insufficient disclosure in the patent.
- Claims are not fairly based on the description.
- Insufficient or misleading disclosure to the Patent Authority.
- The defendant or the revocation applicant owns the invention (in practice, a patent owner seeks amendment of ownership in such circumstances).

A patent can also be revoked at the request of the patentee or due to failure to pay renewal fees in time.

22. When is a patent infringed? How is a claim for patent infringement made and what remedies are available?

A patent is infringed through any unlawful exploitation of an invention (subject matter of the patent), namely:

- If the invention is a product: manufacturing, using, offering for sale, selling or importing for the purpose of any of these activities.
- If the invention is a process: using the process and, in relation to a direct product of the process, engaging in all activities considered an infringement in relation to an invention which is a product.

The following activities are not considered exploitation:

- Activity which is not on a commercial scale and not of a commercial nature.
- Experimental use for the purpose of improving an invention or developing another invention.
- Experimental use for the purpose of obtaining a marketing authorisation for the product, the intended marketing activity to take effect after expiration of the patent, subject to specific conditions, as set out in the Patents Law.

Infringement is assessed by reference to the patent claims, which are interpreted in light of the description in the specifications and are given a purposive interpretation. Infringement can also be found where the invention is exploited in a manner similar to that defined in the claims and involving the main features defined in the claim. The doctrines of equivalents or variants apply.

Claims for Patent infringement are filed with the District Court.

The remedies available are:

- Injunction (including interim injunction).
- Compensation (damages, account of profits or reasonable royalties).
- Delivery-up (in exceptional circumstances).
- Costs.

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

Applicable legislation includes the Trade Marks Ordinance (New Version) 1972 (TM Ordinance) and the Trade Marks Rules 1940. Some aspects of trade mark rights or related rights are protected by common law.

Brands of Preparations can be registered as trade marks, similarly to other product brands. However, international non-proprietary names (INNs) are not registerable.

Trade marks are registered for marks, consisting of letters, numerals, words, devices or other signs, or a combination of these, whether in two or three dimensions, used or intended to be used by the applicant in relation to goods produced or marketed by him, which are adapted to distinguish the goods or services of the applicant from those of others. Marks must be distinctive, either inherently or through use.

Where a mark is registered as a trade mark in a country of origin that is a party to the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention), or a member of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS), the Registrar of Trade Marks (Registrar) does not refuse to register the same mark (*telle quelle*), save in specific circumstances.

Well-known trade marks are also protected under the TM Ordinance.

24. How is a trade mark registered? In particular:

- To which authority must the application be made?
- What fee is payable?
- What are the key stages and timing?

The authority

Applications to register a trade mark in Israel are filed with the Trade Marks Office (www.justice.gov.il/MOJEng/RashamPatentim/TradeMark).

Fee

Every class contemplated is a separate and individual application. The official fee, per application, is NIS1,446 (about US\$380).

For a complete fee schedule, see www.justice.gov.il/MOJEng/RashamPatentim/TradeMark/Fees.htm.

Process and timing

Examination starts about 12 to 15 months from filing. All applications undergo formal and substantive examination (including of third party rights).

The examination process must be completed, and the application placed in a condition for acceptance, within two years from commencement of examination. Failing this, the application file can be closed, unless the applicant requests a hearing before the Registrar to present its arguments to support acceptance of the application.

Applications are published in the Trade Marks Journal following acceptance, and before registration, when the three-month opposition period commences. If no opposition is filed, the mark proceeds to registration.

25. How long does trade mark protection last? How is a trade mark renewed?

For trade marks registered until 7 August 2003, registration lasts for seven years, from the date of filing the trade mark application (Initial Period). For trade marks registered on or after 7 August 2003, the Initial Period of protection is extended to ten years (rather than seven years). Currently, all trade marks can be renewed for further consecutive 14-year periods (Renewal Periods), without limitation, on or three months before expiry of each such term, by paying the applicable renewal fees.

Under an amendment of the TM Ordinance, Renewal Periods for all trade marks will be amended to ten (instead of 14) years. This provision will only become effective three months after the date of Israel's entry as a party to the WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol) (the date of joining has yet to be published).

26. In what circumstances can a trade mark be revoked?

A revocation application can be submitted to the Registrar within five years of registration of the trade mark, on the grounds that either:

- It is not eligible for registration.
- It creates unfair competition in Israel.

An application for revocation on the ground that it was not filed in good faith can be filed at any time.

In addition, an application for revocation can be submitted by any interested person, on the grounds that no bona fide intention existed to use it, or lack of use during the three years preceding the revocation application (provided that the non-use was not due to special circumstances in the trade).

27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Infringement of a registered trade mark means the use by a person not entitled to it of:

- A registered trade mark, or of a mark resembling the trade mark, in relation to goods in relation to which the trade mark is registered or to goods of the same description.
- A registered trade mark in advertising goods of the class in relation to which the mark is registered or in relation to goods of the same description.
- A well-known mark, even if not registered, or of a mark confusingly similar to it, in relation to goods for which the mark is known, or in relation to goods of the same description.
- A well-known mark which is registered, or similar to it, in relation to goods which are not of the same description, provided that such use would indicate a connection between those

goods and the owner of the registered mark, and the owner of the mark is likely to be harmed as a result of such use.

A claim for trade mark infringement can be filed (only by the registered proprietor of the trade mark) with the District Court.

Civil remedies available include:

- Injunction (a restraining order).
- Damages/account of profits.
- Delivery-up.
- Destruction of goods.
- Costs.

Criminal proceedings can be brought by the proprietor of the registered trade mark by filing a private criminal complaint.

28. Is your jurisdiction party to international conventions on patent and trade mark protection?

Israel is a party to international conventions on patent and trade mark protection, including the:

- Paris Convention (Stockholm text).
- PCT.
- TRIPS.

PRODUCT LIABILITY

29. Please give an overview of medicinal product liability law, in particular:

- Under what laws can liability arise (for example, contract, tort or statute)?
- What is the substantive test for liability?
- Who is potentially liable for a defective product?

Legal provisions

Liability can arise under any of the following laws and causes of actions:

- The Civil Wrongs Ordinance (New Version) 1968 (CWO), in particular, torts of negligence and breach of statutory duty.
- The Defective Products (Liability) Law 1980 (DPL).
- The Contracts Law (General Part) 1973 (Contracts Law).
- The Consumer Protection Law 1981 (CPL).
- General offences, such as causing death or severe injury due to negligence, as governed by the Penal Law 1977.

Substantive test

Tort. The elements of negligence consist of:

- A duty of care.
- Breach of the duty.
- A causal connection between the breach and the claimed damage.

To establish breach of statutory duty, a plaintiff (claimant) must prove breach by the defendant of a duty imposed on him by any law or regulation other than the CWO, provided that, the purpose of the other law or regulation is to protect or benefit the claimant, and that the damage caused due to the breach is of the nature contemplated by law or regulation.

DPL. This only applies where the injured party suffers bodily injury and imposes strict liability, subject to limited and specific defences (see *Question 31*), on manufacturers that manufacture defective products.

Contracts Law. Both the Contracts Law and the Sale Law 1968 (Sale Law) include certain provisions according to which:

- A party to a contract must not mislead the other party.
- Both parties must perform the contract in good faith and in a customary manner.

Further, according to the Sale Law, a seller is not deemed to have fulfilled his obligations under a contract if, for example, he delivers a product that does not meet the quality required for its normal or commercial use, or for the purpose of the contract.

CPL. This provides, among other things, that a dealer must not do anything, by act or omission, likely to mislead a consumer as to any matter material to a transaction, including in relation to the:

- Quality and nature of the product.
- Use that can be made with the product and the risk associated with it.
- Manner of handling the product.
- Conformity of the product to a standard, specification or model.

The CPL also imposes a disclosure duty, including in relation to defects and inferior quality. Any act or omission contravening these provisions is an offence under the CWO, and breach of certain provisions of it can also result in criminal liability.

Liability

Torts. Anyone in the supply chain, including a manufacturer, importer, distributor, seller and any other person connected with the supply of a defective product, can be liable, subject to the substantive requirements being met (see *above*, *Substantive test: Tort*).

DPL. Liability lies with the manufacturer, namely a person who engages, for commercial purposes, in the manufacture or assembly of products, including:

- A person who represents himself as the manufacturer by using his name or trade mark or in any other manner.
- The importer, for commercial purposes, of a product manufactured abroad.
- The supplier of a product whose local manufacturer or importer is not easily identifiable.

Contracts Law. A cause of action probably only exists against the immediate party to the contract, such as the supplier of a Preparation.

CPL. Liability lies with the dealer, namely a person who sells a commodity or performs a service by way of trade, including a manufacturer (see *also Question 33*).

THE REGULATORY AUTHORITIES

Pharmaceutical Administration

T +972 2 5681212/3
F +972 2 6725820
W www.health.gov.il/drugs

Main areas of responsibility. Control of pharmaceutical and medical products, cosmetic products and medical equipment, and developing national policy relating to Preparations.

Registry of Preparations, Pharmaceutical Administration

T +972 2 5681342/49/37
F +972 2 6725820

Main areas of responsibility. Registering Preparations in Israel, to protect public health and facilitate marketing of safe and effective Preparations. Devises policy relating to registration, marketing, approval of advertising and so on of Preparations.

Clinical Trials Department, Pharmaceutical Administration

T +972 2 5681360/217
F +972 2 6717318
E nili.yakobov@moh.health.gov.il
keren.rahamim@moh.health.gov.il
(administrative co-ordinators)

Main areas of responsibility. Approval and regulation of clinical trials in Israel.

Institute for Standardisation and Control of Pharmaceuticals, Pharmaceutical Administration

T +972 2 6551702/17
F +972 6551777

Main areas of responsibility. Responsible for ensuring the safety of Preparations marketed in Israel. Supervises locally manufactured and imported biological and chemical Preparations for human and veterinary use.

30. What are the limitation periods for bringing product liability claims?

The limitation period for civil actions, including product liability matters, is seven years, and begins on the date the cause of action occurs. There are circumstances where the limitation period can be extended.

The DPL provides for a shortened limitation period of three years. In addition, an action under the DPL can only be brought within ten years from the end of the year in which the product left the manufacturer's control.

31. What defences are available to product liability claims?

Defences available to the manufacturer under the DPL include:

- That the defect arose after the product left the manufacturer's control.

- That in accordance with the state of scientific and technological development at the time the product left the manufacturer's control, he could not have known that, in relation to its design, the product did not meet reasonable safety standards (a similar defence also applies where a claim is based on the CWO). This defence may be excluded where the manufacturer's actions or omissions amount to breach of his post-sale duties.
- That the manufacturer had not intended the product to leave his control, and took reasonable steps to prevent it leaving his control and to warn the relevant section of the public of the associated risk.
- Voluntary exposure to risk, provided that the injured party is no less than 12 years old.

Defences available to claims based on the CWO or the CPL are:

- The damage was caused by an unforeseeable extraordinary natural event, or that the fault of another person was the decisive cause for the damage.
- Voluntary exposure to risk (does not apply where the cause of action is breach of statutory duty, or where the injured party is less than 12 years old).
- The action disputed was committed according to a legislative enactment (does not apply where the cause of action is negligence).
- Injured party's failure to mitigate his damages or contributory fault.
- The damage was caused by a trivial act.

Where the product liability claim is contractual, the defences may also be based on the provisions of the specific contract, such as a provision allowing only for agreed compensation.

32. What remedies are available to the claimant?

Remedies available include compensatory damages for:

- Bodily (including psychological) injury: pecuniary (such as the loss of capacity to earn money also during the lost years) and non-pecuniary (pain and suffering and reduction of life expectancy).
- For negative feelings, feelings of disgust or harming the consumer's autonomy, provided that the damages or feelings are not *de minimis*.
- For damage to property or products (usually unrelated to Preparations).

Damages can be limited in view of the defences (*see Question 31*), (for example, failure to mitigate the damage and contributory negligence).

The DPL includes specific limitations on the amount of damages (relating to non-pecuniary damages, loss of earnings and loss of earning capacity).

Generally, punitive damages are also available under tort law. Without specific legislation defining a clear rule when the court will award punitive damages, courts are only likely to award punitive damages in rare circumstances, and only where the offender acted in malice.

The CPL authorises a court to award exemplary damages up to NIS10,000 (about US\$2,650) for certain breaches of the CPL.

Only one of these can be regarded as related to product liability.

33. Are class actions allowed for product liability claims? If so, are they common?

A class action is potentially available to product liability claimants. A court can generally only approve a class action if the following conditions are met:

- There are material questions of fact or law that are common to the class, and there is a reasonable likelihood that those questions will be decided in favour of the class.
- The mechanism is a fair and efficient way to resolve the conflict.
- There is a reasonable likelihood that the interests of the entire class will be properly represented and administrated.
- It is reasonable to assume that the interests of the entire class will be represented and administrated in good faith.

Over the last few years, there has been a growing awareness in Israel, whereby claimants have been more willing to file class actions in connection with product liability issues.

REFORM

34. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

The proposed Monetary Law (Civil Codex) is being finalised into a binding law, replacing most of the current civil legislation, including the DPL, the CWO and the Contracts Law, to create coherence among the various civil laws. Expected relevant changes include a broader definition of the term defective product, and extending the limitation period under the DPL from three to four years.

A Clinical Trials Bill is also being finalised. The proposed law aims to regulate, in primary legislation, issues currently being regulated by MOH guidelines, and to update existing provisions and regulate unregulated issues.

Israel is a signatory to the Madrid Protocol. New regulations implementing the Madrid Protocol were published at the beginning of 2007, and will become effective three months after Israel's entry as a party to the Madrid Protocol. The date of entry has yet to be published.

Israel is expected to move to the publication of patent applications within 18 months from the priority date (rather than on their acceptance by the Patent Authority). Under the proposed amendment, damages for patent infringement, based on reasonable royalties, could be claimed, retroactively, once the patent is issued. This compensation could be claimed, in certain circumstances, in relation to infringing activities occurring as of the publication date.

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advocates, notaries and patent attorneys



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