Life sciences in Hungary: overview

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A Q&A guide to life sciences law in Hungary.

The Q&A gives a high level overview of key issues including pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, patents, trade marks, and product liability.

To compare answers across multiple jurisdictions, visit the *Life Sciences Country Q&A tool*.

This Q&A is part of the PLC multi-jurisdictional guide to life sciences. For a full list of jurisdictional Q&As visit *www.practicallaw.com/lifesciences-mjg*.

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Regulatory overview

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

The authorisation framework for medicines, including biologicals, is provided by Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (Medicine Act). The Medicine Act governs clinical trials, manufacturing, marketing authorisation, pharmacovigilance, wholesale distribution, parallel imports, brokering of medicinal products, and product liability.

Medical devices, including medical appliances, are regulated by Decree No. 4/2009 (III. 17.) and Decree No. 7/2004 (XI. 23.) of the Minister of Health.

Pricing and reimbursement is governed by Act XCVIII of 2006 on General Provisions relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Appliances and on the Distribution of Medicinal Products (Drug Economy Law), which also covers drug advertising and promotion, and retail (pharmacy) distribution.

Regulatory authorities

The main regulatory authorities are the:

- National Institute for Quality and Organisational Development in Healthcare and Medicines (GYEMSZI).

- National Health Insurance Fund (OEP).

Biotechnology and combination products

Biotechnology products (biologicals) must be centrally authorised for marketing by the European Commission (Commission) under Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation).

Under Hungarian law, specific rules apply to the pricing and reimbursement of biologicals and combination products.

Pricing and state funding

2. What is the structure of the national healthcare system, and how is it funded?

The national healthcare system is part of the social insurance risk sharing scheme. Healthcare benefit eligibility follows from compulsory participation in the social insurance scheme and includes healthcare services, medicines free of charge and/or for full or part payment, and certain cash benefits such as sick pay.

Besides employers' and employees' contributions, the healthcare budget is also funded from specific payment obligations on pharmaceutical companies, including:

- A 20% clawback tax on the producer price of medicinal products sold in pharmacies with social security reimbursement. This is based on the amount of reimbursement shown under the volume of sales under prescription for the month, payable principally by marketing authorisation holders.

- Additional 10% calculated and paid on the same basis as the 20% clawback tax. This is for medicinal products reimbursed for at least six years whose price accepted for public reimbursement exceeds HUF1,000, if no other reimbursed medicine is available with the same active substance and form distributed under a different brand name and by a different marketing authorisation holder.

- 2.5% of the monthly amount of wholesale margins from the sale of reimbursed medicines to pharmacies, payable by authorised wholesalers.

- Payments under the price volume agreements concluded between OEP and marketing authorisation holders (*see Question 4*).

- Monthly fees of HUF832,000 and/or HUF83,000 per person respectively, paid by pharmaceutical companies for the drug promotion activities performed by their medical sales representatives, related to their medicines and/or medical appliances.

- Payments by marketing authorisation holders in proportion to the reimbursement spent for their products, when the budget allocation is overspent.

3. How are the prices of medicinal products regulated?

Prices of medicinal products must be approved by OEP to obtain public reimbursement. OEP's approval for reimbursement is subject to the following pricing rules.

If the product's active substance has not yet been admitted for reimbursement, the marketing authorisation holder should set the producer price, to not exceed the price of the same medicine (or another medicine with the same active substance) with the lowest price among such products on the market in any EU or European Economic Area (EEA) member state (and the medicinal product is reimbursed in at least three of these states).

If the active substance has already been admitted for reimbursement, and the two products' method of administration is identical, the producer price must be at least 40% lower than the producer price of the other product first admitted for reimbursement (first generic rule). Subsequent rules include that:

- The producer price of the second generic product must be at least 20% lower than that of the first one.
- The third generic product's producer price must be at least 10% lower than that of the second generic.

Price increases are subject to the same approval process, and OEP conducts regular price competitions to generate price reductions.

In the reimbursement system, maximum wholesale and retail sale margins apply, calculated as a certain percentage or a minimum fixed amount of the producer price or the wholesale price. As of 1 August 2012, the maximum rates and amounts of wholesale margins were reduced and complemented with minimum sales values, while those of retail sales margins increased.

When dispensing reimbursed medicines to patients, pharmacies cannot set a price higher than the highest retail price calculated based on the producer price accepted by OEP, nor a reimbursement amount or reimbursed price different from that established by OEP.

In exceptional circumstances, such as temporary supply disruption or the balance of the pharmaceutical market, the government can freeze the prices of medicines as determined in sales contracts between manufacturers and distributors, for a maximum period of two years.

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

The price of medicinal products is reimbursed through the standard reimbursement system or, if not yet approved for standard reimbursement, on a named patient basis.

Medicinal products are approved for standard reimbursement by OEP on application by the marketing authorisation holder. The conditions for approval are:

- Valid marketing authorisation.
- Cost efficient use.
- Economic and effective availability of the medicine.

- The marketing authorisation holder's commitment to bear certain insurance costs.
- Available (or potentially available) social security funding resources.
- The marketing authorisation holder's commitment to market and hold stocks of the product.
- Compliance with the relevant pricing rules (*see Question 3*).
- Payment by the marketing authorisation holder of an application fee of HUF1.5 million.

The standard reimbursement system includes two main reimbursement categories, such as:

- Indication based reimbursement at 100% (special) and 90%, 70% or 50% (premium) reimbursement rates.
- Normative reimbursement at 80%, 55%, 25% or 0% reimbursement rates.

In any reimbursement category, OEP can apply any of the following reimbursement methods:

- Percentage-based reimbursement.
- Fixed amount reimbursement based on the active substance or the therapeutic efficacy.
- Price volume agreement (PVA) with the marketing authorisation holder for a maximum term of four years, whereby the marketing authorisation holder will make payments based on number of batches sold, limit value, therapeutic efficacy, and compliance. PVA is mandatory if the product contains an active substance not yet approved for reimbursement, or the application concerns an indication which has not yet been approved for special (100%) or maximum percentage rate premium (90%) reimbursement.
- Contract for the special reimbursement of medicines purchased through public procurement.
- Reimbursement limited to a specific amount or reduced by a specific amount or percentage.
- Different percentage-based or limited amount reimbursement, depending on patient compliance.
- Reimbursement based on the maximum reimbursed price.

Reimbursement is accorded to the gross consumer price, meaning that eligible patients only pay the reimbursed price, and OEP directly reimburses pharmacies for the reimbursement amount.

Manufacturing

5. What is the authorisation process for manufacturing medicinal products?

Application

Applications for manufacturing authorisations must be submitted to GYEMSZI.

Conditions

Applicants must fulfil specific conditions regarding their personnel and technical equipment, to ensure that the quality of the manufactured medicines complies with the requirements determined in the marketing authorisation. Manufacturers must carry product liability insurance and employ a qualified person responsible for batch release and quality assurance.

Restrictions on foreign applicants

Manufacturing authorisation is only granted to businesses organised or recognised under Hungarian law, or to Hungarian branch offices of companies registered abroad.

Key stages and timing

On receipt of an application for manufacturing authorisation, GYEMSZI conducts a site inspection and examines whether the applicant:

- Meets the mandatory personnel and technical requirements.
- Has an appropriate documentation and quality assurance system.

GYEMSZI issues a decision within 90 days of receipt of the application. The manufacturing authorisation is issued for specific manufacturing sites, medicines and/or pharmaceutical forms and activities. GYEMSZI registers the manufacturing authorisation in the European Medicines Agency (EMA)'s database.

Fee

The fee for the inspection is HUF450,000 per site. Manufacturing authorisation is subject to a HUF225,000 fee.

Period of authorisation and renewals

Manufacturing authorisations are valid for an unlimited period of time (unless withdrawn).

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

GYEMSZI monitors compliance with obligations related to the production of medicines, active substances and excipients, and has powers to:

- Request information.

- Inspect the manufacturing site.
- Collect samples and retain samples at the manufacturer's expense.

Imposing penalties

If GYEMSZI finds misuse or deviation from the manufacturing authorisation, it can:

- Order cessation of the violation.
- Prohibit further violation.
- Order or initiate withdrawal from commercial circulation of a medicine or production batch presenting risk to life, health or physical safety.
- Order the manufacturer to eliminate deficiencies within a specific timeframe, and suspend authorisation until deficiencies are eliminated.
- Withdraw the manufacturing authorisation for repeat violations or violations presenting a serious threat to public health.
- Impose a minimum fine of HUF100,000 (there is no maximum amount of fine).

Clinical trials

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are governed by the Medicine Act and by:

- Government Decree No. 235/2009 (X. 20.) on the Procedural Rules of Authorisation of Medical Researches Involving Human Subjects, Clinical Trial of Investigational Medicinal Products for Human Use, and Clinical Trial of Medical Devices for Human Use Intended for Clinical Investigation.
- Decree No. 35/2005 (VIII. 26.) of the Minister of Health on the Clinical Trial of Investigational Medicinal Products for Human Use and on the Implementation of Good Clinical Practice.
- Decree No. 33/2009 (X. 20.) of the Minister of Health on the Clinical Trial of Medical Devices.

GYEMSZI has jurisdiction over investigational medicine, and the Office of Health Authorisation and Administrative Procedures (EEKH) for medical devices.

Authorisations

Clinical trials are subject to regulatory authorisation. The applicant must pay a fee of HUF580,000 for the clinical trial of an investigational medicine, and HUF500,000 for the clinical trial of a medical device.

GYEMSZI or EEKH issues authorisation based on an evaluation of the clinical trial documentation (protocol, informed consent form and so on), and the professional opinion of the Medical Research Council Ethics Committee for Clinical Pharmacology, or the Medical Research Council Scientific and Research Ethics Committee, respectively.

Consent

Before enrolment, trial subjects must voluntarily sign an informed consent statement. The statement must correspond with the information the investigator delivers to the trial subjects both orally and in writing, including the details and process of the trial in Hungarian or in another language the trial subjects understand.

Trial pre-conditions

The sponsor or its authorised representative must be organised in an EEA member state (or a country with equal status). For investigational medicines, the sponsor must carry sufficient liability insurance issued by an EEA established insurance company.

Procedural requirements

The sponsor must notify the competent authority of the start of the clinical trial. Investigators must monitor and document the health condition of trial subjects before, during and after the trial, and continuously report all adverse events to the sponsor. The sponsor must keep records of these adverse events, and immediately report all serious adverse reactions to GYEMSZI or EEKH.

Any amendment to the trial protocol must be reported to GYEMSZI or EEKH. Substantial modifications are subject to re-authorisation.

The sponsor must notify GYEMSZI or EEKH within 90 or 30 days of the completion of the trial. Sponsors must retain the trial documentation for at least five years.

Marketing

Authorisation and abridged procedure

8. What is the authorisation process for marketing medicinal products?

Application

National marketing authorisation applications are submitted to GYEMSZI. Applications for centralised marketing authorisation issued by the Commission are submitted to the EMA.

Authorisation conditions

Marketing authorisation is granted if the applicant is organised in the EEA and if the:

- Qualitative and quantitative composition (including the manufacturing process) of the medicine is known and established.
- Therapeutic efficacy has been clinically substantiated.
- The risk-benefit balance is favourable.

Other conditions

After obtaining marketing authorisation, the marketing authorisation holder must inform GYEMSZI of the actual launch date of the product. Before this date, the marketing authorisation holder must send a final sample to GYEMSZI for inspection.

The marketing authorisation holder is responsible for launching the product on the Hungarian market and must ensure that its contracted distributors continuously have an adequate supply. If the product is unavailable on the Hungarian market for three consecutive years, GYEMSZI can unilaterally declare the marketing authorisation withdrawn.

Key stages and timing

Following its review of the application, GYEMSZI can request the applicant to amend the documentation, within 15 days of this request.

Up to 90 days after submission, GYEMSZI can request the applicant to reply, within 15 days, to any questions posed during the review process. After then, GYEMSZI prepares an assessment report, and issues a decision within 210 days from the initial marketing authorisation submission date.

At the time of issue of the marketing authorisation, GYEMSZI sends a notice to the Commission and posts the assessment report on its website.

Fee

There are different marketing authorisation fees according to the type of application and the medicine. Fees for authorisation or marketing authorisation extension of an allopathic medicine (except allergens) in the national procedure are as follows:

- For an original product: HUF1.35 million.
- For a generic or other product: HUF675,000.

Period of authorisation and renewals

Marketing authorisations are effective for five years. Applications for renewal must be submitted at least nine months before expiration. GYEMSZI renews marketing authorisation for an unlimited period unless it decides, based on pharmacovigilance data or insufficient patient exposure, to renew it for only one

more five year term.

Post-marketing commitments and pharmacovigilance obligations

For reasons of risk related to the product's safety, GYEMSZI can issue the marketing authorisation subject to one or more of the following conditions:

- Implementing measures to ensure the safe use of the medicine in the risk management system.
- Post-authorisation safety studies.
- Recording or reporting suspected adverse reactions according to stricter rules than those stipulated by law.
- Any other conditions or restrictions regarding the safe and effective use of the medicine.
- An appropriate pharmacovigilance system.
- Post-authorisation efficacy studies, taking into account scientific guidance from the EMA, where concerns relating to some aspects of the medicine's efficacy are identified, and can only be resolved after the medicine has been marketed.

Marketing authorisation holders must:

- Operate a pharmacovigilance system designed to monitor product safety and detect any change to the risk-benefit balance.
- Employ a person responsible for pharmacovigilance.
- Record, examine and report any suspected adverse reactions through the EMA's EudraVigilance database (*http://eudravigilance.ema.europa.eu/highres.htm*).
- Operate a risk management system for each of their products to identify, characterise, prevent or minimise risks.

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

An abridged procedure can apply to products for which both:

- Qualitative and quantitative composition of active substances and pharmaceutical form is the same as those of the reference medicine.
- Bioequivalence with the reference medicine has been shown with appropriate bioavailability studies.

These generic products are authorised for marketing upon applications that rely on the results of pharmacological, toxicological or other pre-clinical and clinical studies of the reference medicine, if the reference medicine has already been authorised for marketing in the EEA or by the Commission for at least eight years.

Similar abridged procedures are available for similar biological products and medicines with well-established medicinal use in the EEA for at least ten years.

Homeopathic medicines and traditional herbal medicines can be authorised in a simplified marketing authorisation procedure, requiring simpler documentation, if certain legal requirements are met (*see Question 17*).

10. Are foreign marketing authorisations recognised in your jurisdiction?

On request, GYEMSZI can recognise in Hungary (as concerned member state (CMS)) a marketing authorisation holder's marketing authorisation issued in another EEA member state (as reference member state (RMS)).

The marketing authorisation holder must first ask the RMS's competent authority to update the assessment report on the medicine, and send it to the applicant and to GYEMSZI.

Unless it presents a serious risk to public health, GYEMSZI approves the assessment report, the summary of product characteristics, the labelling and the package leaflet within 90 days following receipt, and notifies the RMS accordingly.

GYEMSZI issues the marketing authorisation within 30 days after the RMS closes the procedure and the applicant submits the Hungarian language documentation.

For patient care interests deserving special consideration, GYEMSZI can authorise on its own initiative the marketing of a medicine already authorised for marketing in the EEA.

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

GYEMSZI monitors compliance with the obligations related to the marketing of the medicine, including pharmacovigilance, and has general powers to request information and conduct quality control tests.

Imposing penalties

For violation of a marketing authorisation, the same penalties apply as those for violation of a manufacturing authorisation (*see Question 6*).

GYEMSZI can also suspend marketing, and prohibit the use of a medicine, if any of the following apply:

- It is harmful or lacks therapeutic efficacy.
- The risk-benefit ratio has changed and creates doubts concerning safe use.

- Its qualitative and quantitative composition does not comply with the specifics of the marketing authorisation.
- The controls on the constituents or the controls at an intermediate stage of the manufacturing process have not been carried out, or some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled.
- The information supporting the marketing authorisation application or renewal application is incorrect or has not been amended.
- The marketing authorisation holder fails to submit a timely application for modification of the marketing authorisation.
- It is necessary to comply with a request from the Commission.

The scope of marketing authorisation revocation also includes any of the following:

- The cases in any of the first three bullet points above cannot be remedied.
- The marketing authorisation holder fails to eliminate deficiencies within the prescribed deadline.
- The marketing authorisation holder has not met the specific conditions in the marketing authorisation.

GYEMSZI can also suspend or withdraw the marketing authorisation according to a unanimous opinion of the EMA's co-ordination group, or a Commission decision.

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel import activity from elsewhere in the EEA into Hungary is subject to authorisation by GYEMSZI. To be authorised, the medicine must be authorised for marketing in its country of origin, and be either:

- Also authorised for marketing in Hungary.
- A variation of the authorised medicine that can be used for the same therapy, with only minor differences in therapeutic results and quality that do not present a health risk.

If repackaging is required to comply with the Hungarian marketing authorisation it must be done by an authorised EEA manufacturer, or one with a GMP certificate.

GYEMSZI issues parallel import authorisation following application and payment of the HUF500,000 fee. The authorisation is valid for five years and is renewable. The parallel importer must:

- Send the final sample of the first batch to GYEMSZI before placing the product on the market.
- Notify the marketing authorisation holder and GYEMSZI of its intention to import the product, 30 days before the date of the first import.

Intellectual property rights do not apply, but the principles set out by the EU Court of Justice in its judgment in *Case C-348/04* must be observed.

Restrictions

13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Consultancy agreements with healthcare establishments or individual healthcare professionals must not be an inducement to recommend, prescribe, purchase, supply, sell or administer a specific medicine or medical appliance. National restrictions apply outside Hungary if the market practice affects healthcare professionals who exercise their profession in Hungary and are capable of influencing the local market.

Healthcare establishments

Pharmaceutical companies can donate medicine and/or medical appliances for charitable purposes to healthcare and/or social institutions and charitable organisations where professional conditions and controls are in place. Medicine and medical appliance donations must be marked with the following non-removable warnings, respectively:

- "Medicine donation. Not for commercial sale!".
- "Medical appliance donation. Not for commercial sale!".

Other donations and grants are not specifically regulated by healthcare legislation, but under the Code of Ethics (*see Question 15*) these are only allowed if they are all of the following:

- Given for the purpose of supporting healthcare or research.
- Unconditionally given, that is, they are not an inducement to recommend, prescribe, purchase, supply, sell or administer a specific medicine, or an influence over reimbursement decisions, nor a precondition of the aforementioned.
- Documented and recorded by the grantor.

Healthcare professionals

To conduct commercial practices towards healthcare professionals, pharmaceutical companies and their medical sales representatives must be registered with GYEMSZI as promoters.

Promoters can only give gifts, pecuniary advantages or benefits in kind up to the value of 5% of the average monthly minimum wage in any given year (HUF4,900, in 2013), and which relate to the healthcare professional's healthcare activities. Cash rewards are strictly prohibited.

Promoters can only organise promotional events for professional, scientific, or educational purposes. Hospitality is only allowed to the extent it is reasonable in scope and remains subordinate to the main objective of the event. The cost per person per day of hospitality must not exceed 5% of the average monthly minimum wage. Promoters can sponsor professional and/or scientific events or programmes within the relevant hospitality rules.

Pharmaceutical companies can sponsor the participation of persons engaged in healthcare or scientific activities at scientific events or courses in the form of in-kind contributions, which can only cover expenses directly related to attendance at the event (for example, registration fees, travel and accommodation).

For events held at a specific location, both event and participation sponsoring is only allowed if either:

- The resources or expertise constituting the subject matter of the event or necessary for the purpose of the event are only available at that location.
- It would cause disproportionate extra expense to provide the resources or expertise at another location that is closer to the participants' workplace.

Both types of sponsoring must be reported in advance to GYEMSZI.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

Marketing medicines on the internet, by e-mail and by mail order is only allowed for pharmacies and for non-reimbursed, over-the-counter (OTC) products.

Pharmacies must notify their website to the Office of the Chief Medical Officer of the National Public Health and Medical Officer Service (ANTSZ OTH) when the activity starts. The ANTSZ OTH publishes a list of these pharmacies on its website (*https://www.antsz.hu/felso_menu/lakossagi_tajekoztatas/gyogyszerellatas_felugyelete/internetes_gyogyszer_kereskedelem/internet_gyogyszer.html*).

Advertising

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The key legislation is the Drug Economy Law, in addition to implementation Decree No. 3/2009 (II. 25.) of the Minister of Health on the Detailed Rules Applicable to the Promotion of Medicinal Products for Human Use.

As self-regulation, the Code of Ethics for Pharmaceutical Marketing Communications (Code of Ethics) (*http://www.igy.hu/content/_common/attachments/gyogyszer_kommunikacio_etikai_kodexe_en.pdf*) applies to members of the:

- Hungarian Pharmaceutical Manufacturers Association.
- Association of Innovative Pharmaceutical Manufacturers.
- "Védettség" Association of Vaccines and Immunbiological Product Manufacturers and Distributors.
- Hungarian Association of Generic Manufacturers and Distributors.

The Hungarian Authority for Consumer Protection supervises and enforces compliance with drug advertising regulations. Commercial practices towards consumers are also monitored by GYEMSZI and EEKH.

The Competition Authority has jurisdiction over advertising and commercial practices affecting the rules of fair market conditions and competition set out in Act LVII of 1996.

Restrictions

Advertising of prescription medicines and reimbursed medicines is strictly prohibited. It is also prohibited to advertise:

- Medicines unauthorised for marketing in Hungary.
- Medicines containing narcotics or psychotropic substances.
- Investigational medicinal products.
- OTC products bearing the same name as a marketed prescription medicine product.

The advertising of non-reimbursed OTC products must:

- Clearly identify the product as a medicine.
- Display the name of the medicine, and where it contains only one active substance, its international non-proprietary name (INN).
- Encourage the proper use of the medicine.
- Present the medicine according to the summary of product characteristics.
- Contain the general warning: "For risks and side effects please read the patient information leaflet or consult with your doctor or pharmacist!".
- Unambiguously warn of the need to read the patient information leaflet.
- Not be directed towards children.

Certain expressions and references are prohibited. For example, medicine advertising must not:

- Claim or give the impression that medical consultation, treatment or operation is unnecessary.

- Include recommendations from scientists, healthcare professionals or celebrities.

Internet advertising

Advertising medicines over the internet is subject to the same restrictions (*see above, Restrictions*) and the general rules governing internet advertising. The Code of Ethics also regulates internet advertising, websites and e-communication.

Packaging and labelling

16. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

Packaging and labelling is regulated by the Medicine Act and by Decree No. 30/2005 (VIII. 2.) of the Minister of Health on the Labelling and Patient Information Leaflet of Medicinal Products for Human Use. Compliance is supervised by GYEMSZI.

Information requirements

The packaging (labelling) of medicines must include the following:

- The name, strength, pharmaceutical form, and, if applicable, whether it is intended for babies, children or adults, and, if the medicine contains up to three active substances, the INNs.
- The name(s) of the active substance(s) expressed quantitatively per dosage unit or according to the form of administration, for a given volume or weight.
- The number of doses.
- The list of the excipients known to have a recognised effect and included in the detailed guidance of the Commission.
- Information on the administration and, if necessary, the method of administration.
- A warning that the medicine must be stored out of the reach of children.
- Any additional special warning(s), if necessary.
- The expiration date.
- Special storage conditions, if applicable.
- Specific waste disposal instructions.
- The name and address of the marketing authorisation holder and/or its representative.

- The marketing authorisation number.
- The manufacturer's batch number.
- For OTC, instructions for use.

Other conditions

The information must be displayed in Hungarian and in an easily legible, clearly comprehensible manner. The packaging must also contain the medicine's name and, if more than one strength is marketed, the strength in the Braille alphabet.

Traditional medicines

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

Alternative products include homeopathic and traditional herbal medicines.

Homeopathic medicines are prepared from substances called homeopathic stocks, according to the homeopathic manufacturing procedure described by the Hungarian and the European Pharmacopoeias. Traditional herbal medicines are oral, external and/or inhalation preparations that both:

- Have been in medicinal use before the marketing authorisation application date for at least 15 years in the EEA, and for 30 years in total.
- Are intended for use exclusively according to a specified strength and posology, without medical diagnosis, supervision or prescription.

Both homeopathic and traditional herbal medicines may benefit from a simplified marketing authorisation procedure (*see Question 9*). Homeopathic marketing authorisation applications are subject to lower fees than those of allopathic medicines (*see Question 8*).

The packaging (labelling) must:

- Include reference to the medicine's quality as homeopathic/traditional herbal medicine.
- Instruct the user to consult with a doctor (pharmacist) if the symptoms persist.
- For homeopathics, the warning "Homeopathic medicine without approved therapeutic indication".

When traditional herbal medicines are advertised, the general warning (*see Question 15*) must also include the following: "Traditional herbal medicine. Its use in the indications is based on longstanding use".

Patents

18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

The legal conditions for obtaining a patent are governed by Act XXXIII of 1995 on the Patent Protection of Inventions (Patent Act). Inventions must meet the following criteria to be patentable:

- Novelty: does not belong to a prior art.
- Inventive step: not obvious to experts in the art concerned.
- Industrial applicability: can be produced or used in an industrial or agricultural sector.

Scope of protection

The human body, at any stage of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot be a patentable invention.

Elements isolated from the human body or produced by means of a technical process, including the (partial) sequence of a gene, can be subject to patent protection (even if they have a structure that is identical to that of a naturally existing element).

19. How is a patent obtained?

Application and guidance

The Hungarian Intellectual Property Office (HIPO) handles patent protection applications.

The HIPO website provides guidance on the application procedure and fees, in Hungarian and in English (see *www.sztnh.gov.hu/English/szabadalom/nemzeti_ut/szab_eljar.html*

and *www.sztnh.gov.hu/English/szabadalom/nemzeti_ut/szab_dij.html*).

Process and timing

The process commences with filing of the patent application. Subsequently, HIPO examines whether the application meets the following:

- All criteria for securing a priority date.
- The filing and search fees have been paid.
- The description, abstract and drawings have been filed in Hungarian.

The date when HIPO receives the patent application is the filing date, which provides certain protection to the applicant. Afterwards, HIPO conducts a formal examination of the application and performs a novelty search. HIPO publishes the patent application in the *Gazette of Patents and Trademarks*, within 18 months from the earliest priority date.

Following publication, comments can be made, which HIPO evaluates in the substantive examination of the application (patent prosecution). The applicant can request the substantive examination at the latest within six months of notification of the novelty search performance.

Patent protection is granted, retrospectively from the priority date, if the invention and the application meet all requirements. Protection is registered in the patent registry and HIPO publishes an official communication of this in the *Gazette of Patents and Trademarks*.

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

Patent protection lasts for 20 years from the date the patent application is filed and cannot be renewed.

Extending protection

Protection for medicines can be extended for:

- Five years, under Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products.
- Five and half years, for paediatric medicines under Regulation (EC) 1901/2006 on medicinal products for paediatric use.

21. How can a patent be revoked?

A patent is declared invalid with retrospective effect by HIPO, under any of the following conditions:

- The invention was not patentable or was excluded from patent protection.
- The description does not reveal the invention in detail in a manner in which an expert could implement it.
- The subject matter of the patent is broader than indicated in the application.
- The patent was granted to a person who is not entitled to the patent under the Patent Act.

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

Conditions for infringement

A patent is infringed when the patented invention is exploited without authorisation.

Claim and remedies

The following remedies are available for patent infringement:

- Declaration of infringement by a court.
- Order of cessation of the infringement or any act directly threatening infringement, and the prohibition of further infringement by the infringer.
- Order for the infringer to provide information about the persons involved in the production, distribution or fulfilment of the infringing services or goods, and their business relationships for distribution.
- Instructing the infringer to provide proper satisfaction by way of a statement or other means, if necessary with appropriate publicity provided by or covered by the infringer.
- Order for restitution of economic gains obtained by the infringement.
- Seizure of the tools and materials used for the infringement and the goods affected by the infringement.
- Transfer of tools and materials used for and goods affected by the infringement, and recall from commercial circulation or destruction of the tools, materials or goods.
- Compensation for damages under civil law.
- Publication of the judgment at the infringer's expense.

The patent applicant can request a preliminary injunction before submitting the infringement claim. It can also request the relevant customs authority to prevent the infringing goods from entering the market. Patent infringement is a felony in Hungary, punishable by imprisonment and/or a fine.

23. Are there non-patent barriers to competition to protect medicinal products?

The following non-patent barriers apply:

- Under data exclusivity rules, GYEMSZI cannot accept generic marketing authorisation applications (*see Question 9*) for eight years after issue of the original marketing authorisation.
- Market exclusivity adds a further two-year term when generic products cannot be put on the market.
- This ten-year period can be extended with an additional one-year term if the marketing authorisation holder obtains, within eight years of its reference product's marketing authorisation, an authorisation for one or more new therapeutic indications that provide a significant clinical benefit compared to existing therapies.

In Hungary, these barriers do not protect medicines whose marketing authorisation application was submitted before 30 October 2005 to the competent authority of an EEA state or to the Commission.

Special protection is provided for orphan drugs in Regulation (EC) 141/2000 on orphan medicinal products.

Trade marks

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

Legal conditions for obtaining a trade mark are set out in Act XI on the Protection of Trade Marks and Geographical Indications (Trade Mark Act). A trade mark is a sign or combination of signs, as defined in the Trade Mark Act, that both:

- Can be graphically represented.
- Is capable of distinguishing goods and services from other goods and services.

Scope of protection

A medicinal brand can be registered as a trade mark.

The Trade Mark Act lists absolute and relative grounds for refusing trade mark protection. For example:

- An absolute ground is if a sign is in conflict with public order or moral standards.
- A relative ground is if a sign that has later priority is identical to an earlier trade mark, and is registered for identical goods or services.

25. How is a trade mark registered?

Application and guidance

Applications must be submitted to the HIPO. The HIPO website provides guidance on the application procedure and fees in Hungarian and in English (see *www.sztnh.gov.hu/English/vedjegy/nemzeti_ut/index.html* and *www.sztnh.gov.hu/English/vedjegy/vedj_dij.html*).

Process and timing

Trade mark protection commences with the filing of the application and subsequent examination by HIPO, which allocates the filing date and establishes priority. HIPO conducts a formal examination and a search of earlier trade marks, and prepares and sends a search report to the applicant. The application is published in the *Gazette of Patents and Trademarks* at least one month after the search report was sent to the applicant.

HIPO conducts a substantive examination of the application to establish that:

- The sign fulfils the conditions for trade mark protection.
- There are no absolute grounds for refusal.
- The application meets all legal requirements.

Anyone can submit an observation claiming that the trade mark cannot be granted protection due to absolute grounds for refusal (*sections 2 and 3, Trade Mark Act*).

Within three months of the publication, an opposition can be filed challenging the application, referring to relative grounds for refusal (*sections 4 to 6, Trade Mark Act*). HIPO evaluates the opposition and the written reply of the applicant and, if necessary, conducts an oral hearing.

If the applicant prevails, the trade mark is registered and an official communication of this is published in the *Gazette of Patents and Trademarks*. The protection is granted with retrospective effect from the filing date.

26. How long does trade mark protection typically last?

Trade mark protection is granted for ten years from the date of filing, and can be subsequently renewed for an unlimited number of additional ten-year periods. Every renewal is subject to payment of the application fee. Renewal does not involve extension of the lists of goods and services covered, and the trade mark cannot be amended or changed in any way.

27. How can a trade mark be revoked?

Any party can request revocation of a trade mark, including the owner of a trade mark granted earlier, on the basis of relative grounds if:

- The trade mark does not meet the specified legal requirements or is excluded from protection.
- The sign is different from, or the list of goods is more extensive than, that specified in the original application.
- An application for international registration was submitted by a non-eligible person.

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

Conditions

A trade mark is infringed in case of unauthorised use in business operations of a sign:

- Identical to the trade mark in connection with goods that are identical to those for which the trade mark is registered.
- That consumers could confuse with the trade mark due to it being identical to, or similar with, the trade mark or the goods concerned.
- Identical to, or similar with, the trade mark, in relation to goods that are not identical to, or not similar with, those for which the trade mark is registered, if the trade mark has a good reputation in Hungary, and the use of the sign without due cause would be detrimental to, or would unfairly exploit, the distinctive character or reputation of the trade mark.

Claim and remedies

The trade mark owner, an applicant for trade mark protection or, if the trade mark owner fails to claim remedies, the licensee of the trade mark, can submit a claim.

The remedies are the same as those for patent infringement (*see Question 22*).

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

Patent and trade mark licence agreements and payment of royalties to foreign licensors do not have to be approved or accepted by a government or a regulatory body. However, such agreements can be subsequently reviewed by the competition authorities.

Patent and trade mark conventions

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

Patents

Hungary is party to the:

- Paris Convention for the Protection of Industrial Property 1883.
- Patent Cooperation Treaty 1970.

- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.
- European Patent Convention 2000.
- Patent Law Treaty 2000.

Trade marks

Hungary is party to the:

- Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement).
- Protocol Relating to the Madrid Agreement 1989 (Madrid Protocol).
- Common Regulations under the Madrid Agreement and the Madrid Protocol 2004.
- Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks 1973.
- Trade Mark Law Treaty 1994.

Product liability

31. Outline the scope of medicinal product liability law.

Legal provisions

Product liability in general is governed by Act X of 1993 on Product Liability (Product Liability Act). In addition, the Medicine Act also contains certain strict product liability causes of action for medicinal products, which supersede the general rules.

Specific tort and contractual liability rules of Act IV of 1959 on the Civil Code of Hungary (Civil Code) also apply, in cases not governed by specific provisions of the Product Liability Act and the Medicine Act.

Substantive test

A product is considered defective if it does not provide the level of safety which can be generally expected, with special regard to the:

- Purpose of the product.
- Reasonably expected use of the product.

- Information provided in connection with the product.
- Date when the product was first distributed.
- State of prevailing scientific and technical knowledge.

A product is not defective solely because another product providing a higher level of safety was subsequently placed on the market.

Liability

The producer is liable for product defects. With respect to liability, under the Product Liability Act, producers include the following persons:

- Manufacturers of the completed product, a component or any raw material, and persons representing themselves as the producers by putting their name, trade mark or any other distinctive mark on the product.
- Importers.
- Distributors, if the manufacturer or importer of the product cannot be identified, and the distributor fails to inform the injured person, within 30 days on written request by the injured person, of their identity or the identity of any other manufacturer or distributor who supplied the product.

If the medicine is used to prevent the suspected or verified spread of pathogenic agents, toxins, chemical agents or nuclear radiation, according to the *ex officio* or provisionally granted authorisation of GYEMSZI, the state will compensate the injured person, or in case of their death, their dependent relatives (*Medicine Act*).

32. How can a product liability claim be brought?

Limitation periods

A three-year statute of limitation applies for bringing product liability claims, starting when the injured person becomes aware or should have become aware, acting with due care, of the:

- Damage.
- Product defect or reason for the defect.
- Identity of the producer or the importer.

The liability of producers is extinguished ten years after the product was first placed on the market, unless the injured person brought a claim against them before expiration of this ten-year period.

Class actions

Class action suits cannot be brought under Hungarian law. If the subject matter of claims is connected, the court may decide to join pending actions.

33. What defences are available to product liability claims?

Producers can be exempt from liability if they prove any of the following:

- They did not place the product on the market.
- They manufactured the product for non-business purposes or they did not manufacture or distribute the product in the course of their business activities.
- The product was not defective when they put it on the market and the cause of the defect developed later.
- The defect was not recognisable based on the state of scientific and technical knowledge when they first put the product on the market (except in the case of medicines).
- The defect was caused as a result of compliance with the laws and regulations or mandates of the regulatory authorities.

Manufacturers of a component or a raw material can be exempted from liability if they prove that the defect was either:

- Caused by the structure or composition of the completed product.
- The result of instructions of the manufacturer of the completed product.

34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

The claimant can claim compensation for both:

- Pecuniary and non-pecuniary damage incurred by death, bodily harm or health impairment.
- Damage exceeding the HUF equivalent of EUR500 (converted based on the official exchange rate of the National Bank of Hungary on the day the damage occurred) caused by the defective product to other goods, subject to private use or consumption that the injured person generally used for such purposes.

Hungarian law does not allow punitive damages in product liability claims.

Reform

35. Are there proposals for reform and when are they likely to come into force?

Not yet submitted to the Hungarian Parliament but already available at the government's website, a new bill has been prepared to amend 13 different healthcare related laws as of 1 July 2013. Among others, the amendments intend to transpose into Hungarian law certain EU directives, including Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

Regulator details

National Institute for Quality and Organisational Development in Healthcare and Medicines

W *www.gyemszi.hu*

Main areas of responsibility.

These are:

- Registration, marketing, manufacturing and wholesale authorisation, parallel imports and clinical trials.
- Pharmaceutical advertising and promotion.
- Registration of medical sales representatives.

National Health Insurance Fund

W *www.oep.hu*

Main areas of responsibility.

These are:

- Pricing and reimbursement of medicines and medical appliances.
- Price volume agreements with marketing authorisation holders.

Online resources

Official Hungarian legal database

W *https://kereses.magyarorszag.hu/jogszabalykereso*

Description. Official database of effective Hungarian laws and regulations maintained by the state. Information is up-to-date but only available in Hungarian.

Lex Europa

W *http://eur-lex.europa.eu/n-lex/legis_hu/jogszabalytar_form_en.htm*

Description. Maintained by the Publications Office of the EU, N-Lex is designed to provide direct public access and search options to official databases of national laws, including Hungarian law. According to the legal disclaimer, however, it is not guaranteed that the so accessed documents exactly reproduce the officially adopted text.

GYEMSZI

W *www.ogyi.hu/laws_and_regulations*

Description. The website of the GYEMSZI Directorate General of the National Institute of Pharmacy. Unofficial English language texts of the Medicine Act and the Drug Economy Law are accessible here.

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Product Liability and Labelling (http://uk.practicallaw.com/topic3-103-1141)

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Overview of patents (http://uk.practicallaw.comtopic1-107-3660)

Overview of trade marks (http://uk.practicallaw.comtopic4-107-3668)

Practice note

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Article

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