

Hungary

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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. If biotechnology products are treated differently, please specify the differences.

Two statutes govern the regulatory framework for medicinal products for human use:

- **Act XCV 2005:** Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (Medicine Act) covers:
 - clinical trials;
 - manufacturing;
 - marketing authorisation;
 - packaging and labelling;
 - distribution of medicinal products;
 - product liability.

The competent authority is the National Institute of Pharmacy (NIP).

- **Act XCVIII 2006:** 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) regulates:
 - promotion and advertising;
 - the admission of medicine into the social reimbursement system;
 - retail of medicine;
 - pharmacy distribution.

The key regulatory authorities are the National Health Insurance Fund Administration (NHIFA) and the NIP.

Biotechnology and advanced therapy medicinal products are treated differently in the application for EU marketing authorisation (MA) under Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation). Under Hungarian law, biotechnology products belonging to the broader term “biological products” are not regulated separately: the differences are specified under the general rules.

PRICING AND STATE FUNDING

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

As part of the mandatory social insurance system the national healthcare system is based on the risk-sharing scheme of health insurance.

The healthcare budget is essentially funded from mandatory contributions paid by employers and employees, together with further contributions, fines and payments prescribed by law, including the specific payment obligations of pharmaceutical companies consisting of:

- 12% of the monthly amount of social security reimbursement paid for each product sold (with reimbursement in pharmacies apportioned to the rate of the respective producer/import price and gross consumer price), payable principally by the MA holders (MAHs).
- 2.5% of the monthly amount of wholesale margins realised from the sales of reimbursed medicines to pharmacies, payable by the authorised distributors.
- Payments made by MAHs under the price volume agreements concluded with the NHIFA (*see Question 4*).
- Monthly fees of HUF416,000 and/or HUF83,000 per person (as at 1 November 2010, US\$1 was about HUF195.2) respectively, paid by pharmaceutical companies for the drug promotional activities performed by their medical sales representatives in relation to their medicines and/or medical appliances.
- Payments by MAHs in proportion to their sales revenue when the budget appropriation is overspent.

The healthcare system provides health insurance benefits consisting of:

- Healthcare services (inpatient and/or outpatient care, medicines).
- Cash benefits (sick pay).
- Emergency care benefits.

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

Prices of medicines are generally not regulated, except:

- Where reimbursement is granted, retail distributors cannot:
 - dispense reimbursed medicine at a price higher than the highest retail price calculated on the producer price accepted by the NHIFA;
 - differ from the amount of reimbursement and the reimbursed price payable by the patient as established by the NHIFA when dispensing reimbursed medicine.
- Maximum wholesale and retail margins apply to reimbursed medicines, stipulated as fixed amounts or a certain percentage of the producer price or the wholesale price, and are regulated by a decree of the minister responsible for public health.
- To avert or eliminate temporary disruption, or maintain the balance of the pharmaceutical market, the government can freeze the prices of medicines determined in the sales contracts between manufacturers and distributors for a period of up to two years.

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 health insurance system reimburses the price of a medicine if it is admitted into the social security reimbursement system or, if not yet admitted, it is under special consideration on a named patient basis. Reimbursement is granted for the gross consumer price and paid to the pharmacies: eligible patients only pay the reimbursed price.

The NHIFA admits a medicine into the social security reimbursement system upon application and payment by the MAH of a fee of HUF1.5 million. The admission criteria are:

- Valid MA.
- Cost efficient use.
- Economic and effective availability of the medicine.
- MAH's commitment to bear certain insurance costs.
- Available (or possibly available) social security resources.
- MAH's commitment to market and hold stocks of the product.

For active substances not yet approved for reimbursement, the producer price must not be higher than that of the same product with the same active substance in commercial circulation in any EU or European Economic Area (EEA) member state.

Applications for admission can relate to reimbursement under:

- Indication-based categories at reimbursement rates of 100% (special), 90%, 70% or 50% (premium).

- Normative categories at reimbursement rates of 80%, 55%, 25% or 0%.

The NHIFA adopts a non-appealable decision within 90 days of the application (exceptionally within 60 days for generics) and elects one of the following reimbursement methods:

- Percentage-based reimbursement.
- Fixed amount reimbursement based on the active substance or the therapeutic efficacy.
- Conclusion of price volume agreement (PVA) with the MAH for a maximum term of four calendar years when the MAH undertakes a payment obligation based on either:
 - batches sold;
 - limit value;
 - therapeutic efficacy;
 - compliance.
- Special reimbursement for medicines purchased through public procurement.
- Reimbursement reduced by a specific amount or percentage.

A 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.

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?

Application

The application for manufacturing authorisation must be submitted to the NIP.

Conditions

The grant of manufacturing authorisation is subject to specific technical conditions, including personnel and infrastructure as prescribed by the regulations, to ensure that the quality of the medicine manufactured complies with the requirements determined in the MA. To meet these criteria a manufacturer must employ at least one qualified person who is responsible for:

- Quality assessment.
- Batch release.
- Quality assurance.

The manufacturer must hold sufficient liability insurance coverage.

Restrictions on foreign applicants

Foreign applicants fall under the organisational restriction that the NIP can only grant manufacturing authorisation to businesses organised under or recognised by Hungarian law or to the Hungarian branch offices of foreign registered companies.

Key stages and timing

On receipt of the application, the NIP carries out a site inspection and examines whether the applicant:

- Complies with the mandatory personnel and infrastructure requirements.
- Has an appropriate quality assurance system and documentation system.

The NIP issues the manufacturing authorisation within 90 days of the date the application is received and sends a copy to the European Medicines Agency.

Fee

For the site inspection a fee of HUF450,000 per site is payable, and for the issuance of the manufacturing authorisation a fee of HUF225,000 is payable.

Period of authorisation and renewals

The manufacturing authorisation is valid for specific manufacturing sites, medicines and/or pharmaceutical forms and activities, without time limit, until withdrawal.

6. What powers does the regulator have to:

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

The NIP supervises and monitors compliance and has powers to:

- Request data, documents or other information.
- Inspect the manufacturing site.
- Collect samples and retain samples at the manufacturer's expense.

Where the manufacturing authorisation is breached the NIP can:

- Order cessation of the infringement.
- Prohibit further violation of the law.
- Order the withdrawal from commercial circulation of the medicine, or the production batch, deemed harmful to life, health or physical safety.
- Order the manufacturer to eliminate deficiencies within a prescribed deadline and suspend the manufacturing authorisation until this is done.
- For repeated infringements or serious threat to public health, withdraw the manufacturing authorisation.
- Impose a fine at a minimum of HUF100,000.

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 and regulatory authorities

The rules governing clinical trials are contained in the Medicine Act and in:

- Government Decree No. 235 of 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 Intended for Clinical Investigation.
- Decree No. 35 of 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 (Clinical Trial Decree).

The NIP has competence for clinical trials.

Authorisation

Clinical trials can only be conducted with NIP authorisation.

Upon the application and payment of a fee of HUF450,000, the NIP examines:

- The conduct and legal compliance of pre-clinical studies.
- Clinical trials conducted with the trial product before the submission of the application.
- Whether the trial is professionally substantiated and the test methods are suitable for the purposes of the protocol.
- Whether the protocol complies with professional requirements.
- The expected therapeutic risks and benefits.
- The suitability of the trial product for human use with respect to medicine quality.
- The appropriateness of the liability insurance.

The NIP's authorisation is based on the professional-ethical opinion of the Medical Research Council Ethics Committee for Clinical Pharmacology.

Informed consent

The investigator must:

- Inform, both orally and in writing, trial subjects of the details of the trial, covering all issues prescribed by the Clinical Trial Decree.
- Obtain their informed written consent.

Legally accepted representatives give consent for persons with limited legal capacity, though the patient's presumed intentions are also considered.

Where changes are made relating to the trial which affect the written information provided to trial subjects:

- The authorisation must be modified.
- The written information must be modified and re-supplied.
- The informed consents must be re-acquired.

Further conditions and procedural requirements

The sponsor or its legal representative must be established in an EEA member state, or a country granted equal status as these member states under an international agreement with the EU or the EEA.

The investigator must primarily involve patients treated at the institution carrying out the trial, though the recruitment of volunteers of full mental capacity is also possible (subject to the NIP's prior authorisation).

Investigators must continuously report all serious adverse events to the sponsor and the ethics committee of the institution. The sponsor is liable for reporting all "suspected unexpected serious adverse reactions". The sponsor must keep trial documentation for five years following the trial's completion.

Within 90 days of the trial's completion, the sponsor must notify its completion to the NIP. Any modification to the protocol must also be reported to the NIP. Substantial modifications (potentially affecting the safety of trial subjects) are subject to re-authorisation.

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?

Application

An application for a national MA must be submitted to the NIP. For a centralised MA, issued by the European Commission, application is submitted to the EMEA.

Conditions

MA is granted if the applicant is established in the EEA and, regarding the medicine, if:

- The qualitative and quantitative particulars of the constituents are known and declared (including the manufacturing process).
- Its therapeutic efficacy has been clinically substantiated.
- The risk-benefit balance is favourable.

The name of the medicine cannot be the same as any other product already authorised for marketing, or similar to such an extent that it could cause confusion.

Key stages and timing

Following submission of the application, the NIP requests the applicant, if necessary, to complete the documentation within 15 days. On the 90th day following submission of that documentation, the NIP requests the applicant to reply, within 15 days, to any questions raised during the documentation's assessment. The NIP makes a decision within 210 days from the date of submission, and notifies the NHIFA (and for medicines classed as immunological products, the National Centre for Epidemiology) of its decision.

Fee

Fees for the MA differ according to nature of the application and the type of medicine. Fees for allopathic medicine (except allergens) are:

- For the national procedure:
 - for the authorisation of an original product, or for an MA extension for an original product, HUF1,350,000;
 - for a generic or other product, or for an MA extension for a generic or other product, HUF675,000.
- For the mutual recognition procedure, where Hungary is the reference member state (RMS) (the member state whose assessment is recognised as the basis for a marketing authorisation is called the "reference member state", and the recognising member state is called the "concerned member state"):
 - for the authorisation of an original product, or for an MA extension for an original product, HUF3.15 million;
 - for a generic or other product, or for an MA extension for a generic or other product, HUF1.575 million.
- Where Hungary is a concerned member state (CMS):
 - for the authorisation of an original product, or for an MA extension for an original product, HUF2.25 million;
 - for a generic or other product, or for an MA extension for a generic or other product, HUF1.175 million.

Period of authorisation and renewals

The MA is valid for five years. Applications for renewal must be submitted at least six months before the MA expires. The NIP can renew the MA for an unlimited period of time, though if there are "adverse events reports" it can renew for another five-year period only.



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?

The abridged procedure can apply to the MA of generic products. Generic products have both:

- The same qualitative and quantitative composition of active substances as the reference medicine.
- The same pharmaceutical form as the reference medicine.

The bioequivalence with the reference medicine must be demonstrated with appropriate bioavailability studies.

Generic applications can be submitted without pharmacological or toxicological results, or other pre-clinical and clinical studies, if the reference medicine has already been authorised for marketing by the competent authority within the EEA or by the European Commission for either:

- At least eight years.
- At least six years, provided the original application was submitted in the EEA, or with the European Commission, before 30 October 2005.

A simplified MA procedure, requiring simpler documentation, is also available for homeopathic medicines and traditional herbal medicines, provided they comply with Hungarian law in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive).

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

The MAH of a medicine authorised for marketing in another EEA member state (as the RMS) can request the NIP to recognise the MA in Hungary as the CMS. The procedure begins in the RMS, where the applicant requests the competent authority to update the assessment report on the medicine and send it to both the applicant and the NIP.

When considering whether to grant approval, the NIP examines:

- The updated assessment report.
- The summary of product characteristics (SPC).
- The labelling.
- The package leaflet.

Within 90 days following receipt of the documentation above, the NIP makes a decision and notifies the RMS accordingly. Once

the RMS notifies the applicant that the procedure has closed, the applicant submits the Hungarian version of the documentation to the NIP, and the NIP issues the MA within 30 days.

For patient care interests deserving special consideration, the NIP can authorise *ex officio* the marketing of a medicine authorised for marketing within the EEA.

11. What powers does the regulator have to:

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

To monitor compliance, the NIP has powers to:

- Request data or other information.
- Review documents.
- Conduct site inspections.

Monitoring extends to pharma-covigilance related obligations.

The same legal consequences apply for the breach of a marketing authorisation as for the breach of a manufacturing authorisation (see *Question 6*). Where the MAH fails to fulfil its supply obligation, and the medicine authorised for marketing in Hungary is not available in Hungary for three consecutive years, the NIP can withdraw the MA.

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 medicines from within the EEA to Hungary are subject to NIP authorisation. The medicine authorised for marketing in the country of origin must either:

- Also be authorised for marketing in Hungary.
- Be a variation of the authorised medicine, and be used for the same therapy, without differences in therapeutic results and quality (or with such minor differences that they do not present a health risk).

The medicine must be accompanied by a release certificate, issued by the qualified person following its quality assessment.

Repackaging, where necessary to comply with the Hungarian MA, can only be performed in the EEA. Where repackaged in Hungary, it must be repackaged by an authorised manufacturer. Where repackaged in another EEA member state, a GMP certificate must be issued.

Parallel import authorisation is valid for five years, though production batches cannot be distributed after the expiry date. The parallel importer must send the final sample of the first repackaged batch to the NIP before placing the product on the Hungarian market.

Where the parallel importer is not the MAH, it must notify the MAH of its intention to import 30 days before import. Intellectual



property rights cannot be invoked since they do not apply, but the principles enunciated by the EU Court of Justice in its judgment in Case C-348/04 must be observed.

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

Healthcare establishments

Incentive schemes aimed at healthcare establishments, except donations of medicines or medical appliances, are not regulated. Pharmaceutical companies can make medicine and/or medical appliance donations for charitable purposes to those healthcare and/or social institutions and charitable organisations where professional conditions and controls are properly provided. 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!”

The Code of Ethics (*see Question 15*) generally provides that donations and grants are only allowed where all the following apply and they are:

- Made for the purpose of supporting healthcare or research.
- Unconditionally given and do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicine or influence reimbursement decisions.
- Documented and recorded by the grantor.

Healthcare professionals

Pharmaceutical companies can only conduct incentive marketing practices for healthcare professionals qualified to prescribe or supply medicines and medical appliances (HCPs) where the NIP has registered them, and their medical sales representatives, 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 established in any given year (HUF3,900 in 2011), and they must be related to the HCP's healthcare activities. Cash rewards are strictly prohibited.

During events held for promotional purposes, promoters can provide hospitality only to the extent that it is reasonable in scope and remains subordinate to the main objective of the meeting. The cost of per person of hospitality must not exceed 5% of the average monthly minimum wage (*see above*). Promoters can grant direct or indirect support to professional and/or scientific events or programmes within the hospitality rules.

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

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

Mail order, online marketing and the home delivery of drugs are only permitted by pharmacies: they are prohibited for retail shops. Only non-reimbursed over-the-counter (OTC) products can be advertised on pharmacies' websites. Professional rules governing dispensing medicine must always be observed, and medicine must not be supplied to children under the age of 14.

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?
- If advertising over the internet is treated differently, please identify the differences.

The advertising of medicines is governed by the Drug Economy Law and Decree No. 3 of 2009 (II. 25) of the Minister of Health on the Detailed Rules Applicable to the Promotion of Medicinal Products for Human Use and Medical Aids, to the Register of Medical Sales Representatives, and to Business-To-Consumer Commercial Practices Relating to Medicinal Products and Medical Appliances. Background on the specific rules is set out in the general laws on advertising.

The Code of Ethics for Pharmaceutical Communication (Code of Ethics) of the Hungarian Pharmaceutical Manufacturers Association and the Association of Innovative Pharmaceutical Manufacturers also applies as a local code to those manufacturers and distributors of medicines who join these associations.

Enforcement of the law is conducted by the National Consumer Protection Authority and the NIP. In competition matters, the Hungarian Competition Authority has competence.

The advertising of prescription medicines (Rx) and reimbursed medicines (both Rx and OTC) is strictly prohibited.

Non-reimbursed OTC medicines can be advertised with the following restrictions:

- The product must be clearly identified as medicine.
- The name of the medicine, and where it contains only one active substance, its internationally used common name, must be displayed.
- The proper use of the medicine must be explained.
- The medicine must be presented according to the SPC.
- The general warning “For risks and side effects please read the patient information leaflet or consult your doctor or pharmacist!” must appear.



Certain references and expressions are prohibited from advertising, for example:

- Those which claim, or give the impression, that medical consultation, treatment or operation is unnecessary or redundant.
- Recommendations from scientists, HCPs or celebrities.
- Those that suggest that human health could be adversely affected without the medicine.

The advertising of medicines over the internet is subject to the rules detailed above and the general rules governing internet advertising and electronic communication.

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)?

The packaging and labelling of medicines are examined and supervised by the NIP and must comply with the requirements under the Medicine Act and Decree No. 30 of 2005 (VIII. 2) of the Minister of Health on the Labelling and Package Leaflet of Medicinal Products for Human Use (Labelling Decree).

The exterior and the immediate packaging (labelling) of medicines must contain the following information:

- The name, strength, pharmaceutical form of the medicine, and, if applicable, whether it is intended for babies, children, or adults, and, if the medicine contains up to three active substances, the international non-proprietary names.
- 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.
- Number of doses of the medicine.
- The list of the excipients known to have a recognised action or effect, and included in the detailed guidance published by the European Commission.
- Information about, 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 expiry date.
- Special storage precautions, if applicable.

- Specific disposal precautions regarding unused medicine or waste derived from medicines, and reference to any appropriate collection system in place.
- The name and address of the MAH or its representative.
- The registration number of the MA.
- The manufacturer's batch number.
- Where OTC, instructions for use.

The package leaflet must be drawn up in accordance with the SPC and must include the data listed in the Labelling Decree, in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive).

The data and information must be in Hungarian, in an easily legible and clearly comprehensible manner. The name of the medicine and, if more than one strength is marketed, the strength, must also be shown in Braille on the packaging.

TRADITIONAL HERBAL MEDICINES

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

A product is authorised for marketing as a traditional herbal medicine if it has both been in medicinal use for at least 15 years within the EEA, and 30 years in total, before the application date. A simplified MA procedure can apply to traditional herbal medicine (see Question 9). The general rules governing the manufacture and marketing of medicines apply, and the labelling and package leaflet must include additional statements that:

- The product is a traditional herbal medicine for use only in the specified indication(s) based upon long-standing use.
- The user must consult a doctor or a pharmacist if symptoms persist during the use of the product, or if adverse effects not mentioned in the package leaflet occur.

Advertising to the public must contain a general warning (see Question 15) with the following text: "Traditional herbal medicine. Its use in the indications is based upon long-standing use."

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? If process patents only are available for these products and substances, please give details including whether the situation is likely to change. What are the legal criteria to obtain a patent? Which legislation applies?

Patenting of medicines and related substances is governed by Act XXXIII 1995 on the Patent Protection of Inventions. The pharmaceutical patent system switched from process patents to product patents in 1994.

Inventions must meet the following criteria to be patented:

- Novelty: not belonging to a prior art.
- Inventive step: not obvious to persons skilled in the art.
- Industrial applicability: capable of production or use in any industry or agriculture sector.

The human body, at any stage in its formation or development, and the simple discovery of one of its elements, cannot be patented. Elements isolated from the human body, or produced by a technical process, can be patented (even where they have the same structure as those existing naturally).

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?
- Does the patent office operate a deposit system or are applications subject to some form of scrutiny before acceptance?

The authority

From 1 January 2011, patent applications are filed with the Hungarian Intellectual Property Office (HIPO), previously known as the Hungarian Patent Office (see www.sztnh.gov.hu/English).

Fee

A filing and search fee of HUF34,000 (increased by HUF1,700 for each claim above ten claims, by HUF3,400 for each claim above 20 claims, and by HUF5,100 for each claim above 30 claims) must be paid on filing the application. Later in the process, an examination fee of HUF58,000 and a granting fee of HUF32,000 (increased by HUF3,200 for each additional page after the first five pages) must be paid.

Process and timing

Once the application is filed, the HIPO examines whether the application meets the following requirements to accord the filing date:

- The filing and search fee has been paid.
- The description, the abstract and the drawings have been filed in the Hungarian language.

Where the filing date is accorded by the HIPO, that date establishes priority. The HIPO publishes certain basic data on the patent application in its official journal, the *Gazette of Patents and Trademarks (Gazette)*. Following formal examination and a novelty search, the HIPO publishes the application in the *Gazette* after 18 months from the earliest date of priority has expired.

Provisional protection commences with this publication and takes retroactive effect from the filing date. Following publication anyone can submit observations stating that the invention, or the application, does not comply with the legal requirements of patentability. Comments are evaluated during the substantive examination. The HIPO conducts substantive examination on the applicant's request, which must be submitted within six months after the HIPO has communicated the results of the

novelty search to the applicant. Where the HIPO finds that both the invention and the application meet all legal requirements, it grants the patent. Patent protection is definitive once the HIPO's decision has become final and conclusive.

20. How long does patent protection last? How is a patent renewed or patent protection extended? If the patent itself cannot be extended, can the organisation's monopoly rights be extended by other means, such as supplementary protection certificates or (regulatory) data exclusivity periods?

Patent protection lasts for 20 years from filing date. During this time an increasing annual maintenance fee must be paid.

For medicines, protection can be extended under a supplementary protection certificate, issued under Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products and Regulation (EC) 1901/2006 on medicinal products for paediatric use (Paediatric Regulation), for a maximum period of five years (for paediatric medicines, this is extended to five and a half years).

Data exclusivity prevents the NIP from accepting applications for generic medicines for eight years (where the original application was submitted before 30 October 2005, this period reduces to six years (see *Question 9*)). Market exclusivity extends the data exclusivity period by an additional two-year term, during which the generic product cannot be placed on the market. If the MAH of the reference product obtains, within eight years following the MA of the reference product, authorisation for one or more new therapeutic indications which are held to bring a significant clinical benefit in comparison with existing therapies, market exclusivity is extended by an additional one-year period. Market exclusivity applies only if the MA application of the reference medicine was submitted on or after 30 October 2005.

21. In what circumstances can a patent be revoked?

A patent is revoked by the HIPO with retroactive effect from the filing date where either:

- The invention was not patentable or was excluded from patent protection.
- The description does not demonstrate the invention in a clear and complete manner.
- The subject matter of the patent extends beyond the content of the application as filed.
- The patent has been granted to a person who is not legally entitled to it.

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

Patent infringement is the unauthorised exploitation of a patented invention in the course of a trade, and includes:

- Manufacturing, using, putting, or offering to put, into circulation the patented product or a product obtained directly by the patented process, or stocking or importing it for these purposes.

- Using the patented process.
- Supplying, or offering to supply, an unauthorised person with information relating to an essential element of the invention with a view to producing the invention.

The patentee, the applicant whose invention enjoys provisional protection, or, if the patentee has failed to do so, the licensee, can request the Metropolitan Court (the exclusive venue with exclusive jurisdiction) to:

- Declare infringement.
- Order the cessation of the infringement, or any act directly threatening infringement, and prohibit further infringement.
- Order the infringer to provide information about the persons involved in the production and distribution of the infringing goods, and their channels of distribution.
- Instruct the infringer to provide proper satisfaction, if necessary, in the form of sufficient publicity by, or at the expense of, the infringer.
- Order restitution of economic gains obtained by the infringement.
- Seize:
 - the means and materials used solely, or primarily, for the infringement;
 - the goods affected by the infringement.
- Order the transfer of the means and materials used for, or the goods affected by the infringement to specific persons, or recall, withdraw from commercial circulation or order the destruction of such means, materials or goods.
- Order compensation for damages under civil law.
- Order publication of the judgment at the infringer's expense.

A preliminary injunction can also be requested before filing the infringement claim. The patentee can also request the customs authorities to prevent the infringing goods from entering into free commercial circulation. Patent infringement can qualify as a felony under criminal law and be punished by imprisonment.

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?

Medicinal product brands can be registered as trade marks under Act XI 1997 on the Protection of Trade Marks and Geographical Indications (Trade Mark Act).

Trade mark protection is granted to any sign capable of graphic representation (for example, a word, combination of words, graphics, figures and so on), provided it is capable of distinguishing certain goods or services from others. The HIPO refuses to grant protection on absolute or relative grounds specified in the Trade Mark Act because for example either:

- The sign is devoid of a distinctive character (absolute ground for refusal).

- It conflicts with an earlier trade mark (relative ground for refusal).

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

The competent authority for trade mark applications is the HIPO.

Fee

A trade mark application filing fee of HUF74,800 is payable. Where there are three or more classes of trade mark applied for this increases by HUF32,000 per class for the fourth and each subsequent class.

Process and timing

The registration procedure begins with the filing of the application and a similar examination by the HIPO as in patent proceedings (see *Question 19, Process and timing*). Where the filing date is accorded by the HIPO, that filing date establishes priority. Following formal examination, the HIPO conducts a search for earlier trade mark rights and sends the search report to the applicant. Anyone can file an observation claiming that the sign cannot be granted trade mark protection under the absolute grounds for refusal (see *sections 2 to 3 Trade Mark Act*). The HIPO examines *ex officio* whether the sign and the application comply with the legal requirements, and whether there are absolute grounds for refusal. The search report is sent to the applicant, and once at least one month has passed the HIPO publishes the application in the *Gazette*. Within three months following publication, oppositions can be submitted (on payment of a fee of HUF64,000) on the relative grounds for refusal (see *sections 4 to 6, Trade Mark Act*). After the evaluation and written response to the oppositions (and, if necessary, after an oral hearing) the HIPO decides whether the trade mark can be registered.

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

Trade mark protection lasts for ten years from the filing date. The trade mark owner can request the HIPO to renew the protection for additional ten-year periods on payment of the renewal fee, which is the same as filing fee (see *Question 24*). A trade mark can be renewed indefinitely, but the trade mark cannot be changed, and the list of goods or services to which it applies cannot be extended.

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

The HIPO revokes the trade mark on the request of any interested person if:

- The subject matter of trade mark protection does not satisfy the legal requirements or is excluded from trade mark protection.



- The sign protected by the trade mark differs from, or the list of goods extends beyond, the content of the application as filed.
- The international trade mark application has been filed by a person not entitled to it.

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

A trade mark is infringed by unauthorised use in the course of trade of:

- A sign identical to the trade mark in relation to goods which are identical to those for which the trade mark is registered.
- A sign that consumers could confuse with the trade mark because of its identity to, or similarity to the trade mark and the identity or similarity of the goods concerned.
- A sign identical to, or similar to the trade mark in relation to goods which are not identical to, or not similar to those for which the trade mark is registered, provided the trade mark has a reputation in Hungary and the use of that sign (without due cause) would be detrimental to, or take unfair advantage of, the distinctive character or reputation of the trade mark.

The trade mark owner, the applicant for a trade mark application, or, if the owner has failed to do so, the licensee can claim the same remedies, including a preliminary injunction, before the Metropolitan Court as those available for patent infringements, and can also initiate the measures to be taken by the customs authorities and criminal investigation (*see Question 22*).

28. Is there a requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

Licence agreements do not require the approval of any authority, but can be subject to the subsequent investigation by the competition authorities.

29. Is there a requirement for remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

Former restrictions on foreign remittances have been eliminated, and only special tax provisions on royalties apply under the relevant conventions on the avoidance of double taxation.

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

Hungary is party to the following major international conventions, among others, with regard to medicines:

THE REGULATORY AUTHORITIES

National Institute of Pharmacy (*Országos Gyógyszerészeti Intézet*)

T +36 1 886 9300

F +36 1 886 9460

E ogyi@ogyi.hu

W www.ogyi.hu

Main areas of responsibility

- Registration; marketing; manufacturing and wholesale authorisation; parallel imports; clinical trials.
- Supervision of pharmaceutical advertising and pharmaceutical promotion towards healthcare professionals.
- Registration and de-registration of medical sales representatives.

National Health Insurance Fund Administration (*Országos Egészségbiztosítási Pénztár*)

T +36 1 350 2001

F +36 1 298 2413

E oepest@oepest.hu

W www.oepest.hu

Main areas of responsibility

- Admission of medicines into the social security reimbursement system.
- Ongoing supervision of drug pricing.
- Entering into sale and distribution agreements with MAHs.

Patents

- Paris Convention for the Protection of Industrial Property 1883.
- European Patent Convention 2000.
- Patent Cooperation Treaty 1970.
- Patent Law Treaty 2000.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.

Trade marks

- Madrid Agreement Concerning the International Registration of Marks 1891, Protocol 1989, and Common Regulations.
- Trade Mark Law Treaty 1994.
- 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.



PRODUCT LIABILITY

31. 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

Medicinal product liability arises primarily under statute, but the injured person can also claim damages based on the general rules of contract or tort liability (whichever is applicable) laid down in Act IV 1959 on the Civil Code of the Republic of Hungary (Civil Code).

Product liability is generally governed by Act X 1993 on Product Liability (Product Liability Act). With respect to medicines, these general rules are superseded by certain specific strict liability provisions contained in the Medicine Act. What the Product Liability Act does not govern, the relevant provisions of the Civil Code apply to.

Substantive test

A product is considered defective if it fails to provide the level of safety which is generally expected, with special regard to:

- The purpose of the product.
- The use of the product which can be reasonably expected.
- The information provided in connection with the product.
- The date when the product was placed on the market.
- The state of scientific and technical knowledge.

A product is not considered defective purely because another product providing a higher level of safety is subsequently put into commercial circulation.

Liability

The producer is liable for the damages caused by a defect in the product. "Producer" includes:

- The manufacturer of the finished product, a component or any raw material who, by putting his name, trade mark or other distinguishing feature on the product, presents himself as its producer.
- The importer.
- The distributor, if the manufacturer or importer cannot be identified, and he fails to inform the injured person, within 30 days after a written request to do so, of their identity, or the identity of any other distributor who has supplied the product.

Where the medicine is used in response to the suspected, or confirmed, spread of pathogenic agents, toxins, chemical agents or nuclear radiation on an authorisation granted by the NIP *ex officio* (see Question 10) or provisionally, the state will compensate the injured person, or in the case of death, their dependent relatives.

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

Product liability claims have a three-year statute of limitation, starting when the injured person first becomes aware, or with due care should have become aware, of the damage, the defect and the identity of the producer. The producer's liability is extinguished ten years after the placing of the concerned product on the market.

33. What defences are available to product liability claims?

The producer is exempt from liability only if he proves that:

- He did not put the product into commercial circulation.
- He did not manufacture the product for business purpose distribution, or manufacture or distribute the product in the course of his business.
- The product was free from defect when he put it into commercial circulation and the cause of defect developed at a later stage.
- The defect is due to compliance with laws and regulations, or the mandatory provisions of the regulatory authorities.

The manufacturer of a component or any raw material is exempt from liability if it proves that the defect was:

- Caused by the structure or composition of the finished product.
- Caused as a result of the instructions given by the manufacturer of the finished product.

For medicines, producers cannot escape liability by invoking the defence of a lack of scientific and technical knowledge at the time of putting the product on the market.

34. What remedies are available to the claimant?

The claimant can claim compensation for both:

- Pecuniary or non-pecuniary damage incurred by death, bodily injury or health impairment.
- Damage, exceeding the HUF amount of EUR500 converted on the official exchange rate of the Hungarian National Bank effective on the day the damage occurred, caused to goods for private use or private consumption which the injured person generally used for such purposes.

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

The Hungarian legal system does not currently allow class action suits. Under Hungarian procedural law claimants can join their cases in matters where claims arise from the same, or similar,



factual or legal basis, but it is up to the courts to allow the cases to be joined or assess these claims separately and independently from each other.

36. Are punitive damages allowed for product liability claims? If so, are they common? What comment can you make about likely quantum?

Punitive damages are not allowed under Hungarian law.

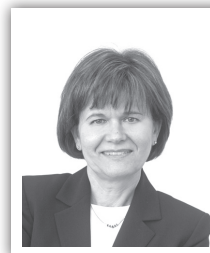
REFORM

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

Amendments to the Drug Economy Law, which came into force on 1 January 2011, put an end to pharmacy liberalisation first introduced in 2007. Authorisation has become subject to specific ownership requirements, and authorised manufacturers and wholesale distributors can no longer acquire ownership in pharmacies that are entitled to dispense medicines with reimbursement.

The payment obligations required from MAHs when the pharma budget appropriations are overspent (*see Question 2*) has changed. Instead of the risk-sharing system diversified on a percentage rate basis between MAHs and the NHIFA, as from 1 March 2011 the surplus will be charged to MAHs in proportion to the social security reimbursement paid for their products in the given calendar year. The Health Insurance Fund will bear only that part of the surplus that would be payable by the MAHs of medicines with the lowest daily therapy cost.

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Areas of practice. Life sciences and pharmaceuticals; corporate and commercial; insolvency; real estate; labour and employment; litigation and arbitration.

Recent transactions

- Representing a client in Hungarian product liability related civil litigation.
- Advising on a consortium agreement regarding the pilot project concerning the tracking and tracing of certain medicinal products in Hungary.
- Advising on the Hungarian law aspects of a multi-jurisdictional exclusive licence and distributorship agreement.
- Advising on the local integration proceedings of two multinational pharmaceutical manufacturers' global merger.
- Advising in negotiations and the preparation of related documents with the National Health Insurance Fund Administration regarding price volume agreements.