GETTING THE DEAL THROUGH

Life Sciences

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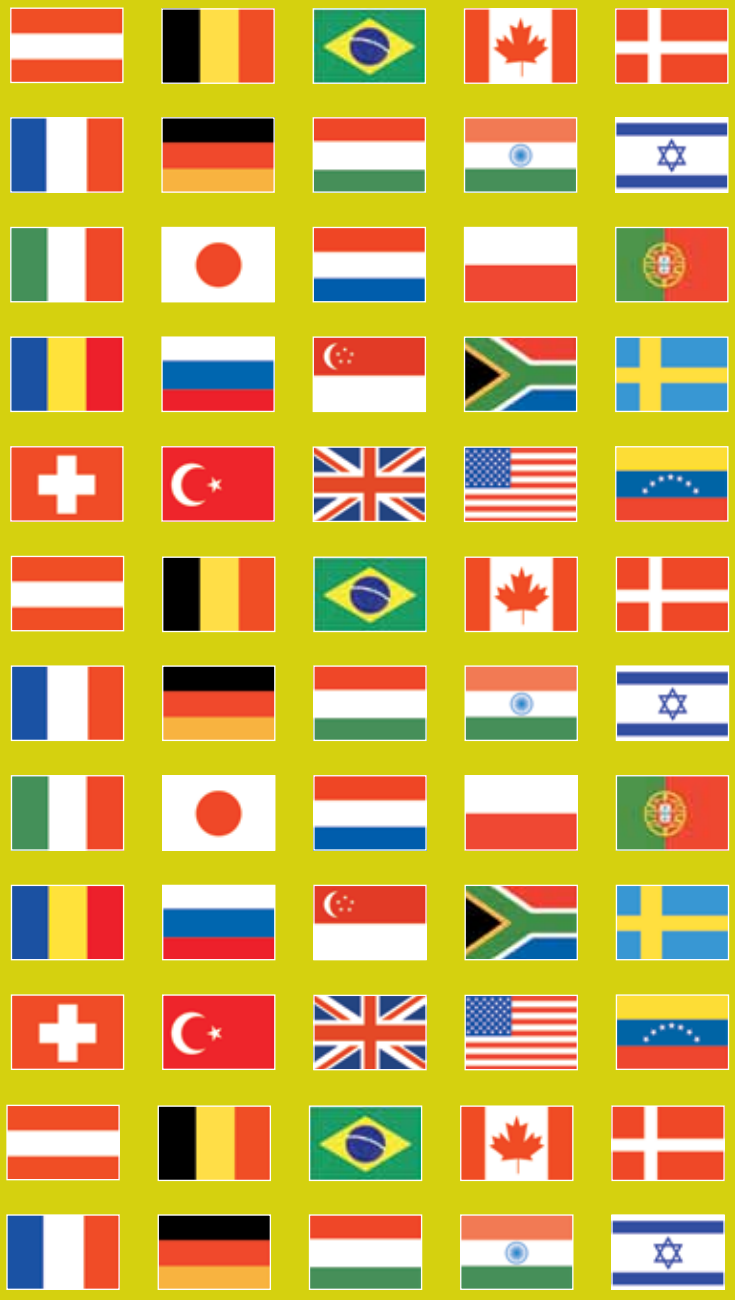
2012

Contributing editors: Alexander Ehlers and Cord Willhöft



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Hungary

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Organisation and financing of health care

1 How is health care in your jurisdiction organised?

The basic principles of the organisation of the health-care system are governed by Act CLIV of 1997 (the Health-Care System Act), more specifically by sections 141 et seq. Pursuant to section 141, the state is ultimately responsible for the state of health of the population, and for the creation of a system that protects, promotes and – if necessary – restores it.

Pursuant to section 143 of the Health-Care System Act, the state organs in Hungary, such as the parliament (as the legislative body), the government, the responsible minister, the state administrative body responsible for health care, health insurers, municipalities, national health councils (NHCs) and regional health councils (RHCs), are charged with the tasks of organising and governing the health-care system. In the interests of promoting and protecting the general health of the population, the state supports and promotes the lawful activities of professional associations and public bodies in the health-care system.

After the redistribution of the responsibilities, the parliament is no longer required to adopt a national health development programme (the NHDP) which was the basis and foundation of the medium-term strategic planning in the health-care sector. Under the current regime, the RHCs adopt regional health development programmes (RHDPs), containing:

- the population of the given region, expected changes of the population and its age-composition, the main factors influencing the populations state of health;
- the expected need for medical services and, according to this, the plans about changing the structure of services;
- the most important professional characteristics, organisational type and ownership structure of providers involved in the obligation to supply health care; and
- plans of renovating and improving the above-mentioned health-care providers.

After adoption, the RHDP is sent to all the region's public health care providers, to the municipalities and to the Minister responsible for healthcare. In accordance with the RHDP, the providers are obliged to make professional plans about the improvement of their services, and send these plans to the competent RHDPs.

2 How is the health-care system financed in the outpatient and in-patient sectors?

The basic principles of the funding of the health-care system are regulated by section 142 of the Health-Care System Act. Pursuant to section 142(1), the state is ultimately responsible for securing the financial coverage necessary for an appropriate medical supply. The supply is ultimately secured by means of both the central governmental budget (as opposed to the budget of the municipal authorities) and the health insurance fund.

More specifically, Act LXXX of 1997 (the Social Insurance Act) elaborates on how to finance the health-care system and with it all sorts of medical care. Pursuant to section 2(1) of the Social Insurance Act, Hungarian citizens and – if certain legislative conditions are fulfilled – residents living in Hungary have to be part of a collective risk-sharing community. This collective risk-sharing is realised by a mandatory social security system that the participants have to support financially according to their income, that is, they have to make contributory payments.

The persons and entities liable for payment and the amount of the payment of the contribution depend on the status and income of the insured person. For instance, if the insured person is an employee, both the employer and the employee are liable to bear a certain percentage of the contribution depending on the income of the employee.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

The general rules of commercial advertising are laid down in Act XLVIII of 2008 on the Basic Requirements and Certain Restrictions of Commercial Advertising Activities. This Act governs issues such as general advertising prohibitions and restrictions, misleading and comparative advertising, et cetera. However, the legislation governing the advertisement of medicinal products in general is Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products.

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

The main rules applying to advertising aimed at health-care professionals are laid down in Act XCVIII of 2006. Pursuant to section 12, the holder of the marketing authorisation of a medicinal product or the authorised distributor of a medicinal product (ie, distributors) and the manufacturer of the medical aid or its authorised representative may engage in promotional activities aimed at professionals (persons entitled to prescribe or distribute or give instructions as to the use of medical products) only after having obtained the relevant authorisation. The National Institute for Quality and Organisational Development in Health Care and Medicines issues the authorisation upon request to distributors of medicinal products or their agents registered in Hungary, and to manufacturers of medical aids or their authorised representatives.

As such, distributors of medicinal products and manufacturers of medical aids or their authorised representatives may engage in promotional activities upon being registered and authorised by the National Institute for Quality and Organisational Development

in Health Care and Medicines. The aforementioned request must indicate – among other things – the name, home address or registered office, and the registered number of the medical sales representative or promoter of medicinal products, including the duration of promotional activities if the medical sales representative wishes to engage in such activities for a fixed period. The holder of the authorisation must forthwith notify the National Institute for Quality and Organisational Development in Health Care and Medicines of any changes in the particulars contained in the application or in the authorisation itself.

The registry of licences contains – among other things – the names of persons carrying out the promotional activities, data on the promoter's qualification and the promoter's declaration that he or she has no conflict of interest. A promoter is deemed to have a conflict of interest if he or she is engaged in the promotion of medicinal products – not including scientific activities under copyright protection – in a medical institution with which he or she has a contractual relationship in accordance with section 7(2) of Act LXXXIV of 2003 on Health-Care Professionals (eg, if he or she is a volunteer, entrepreneur, public servant or clerical person). The aforesaid shall not apply to persons engaged in the network of medical sales representatives of the government body for pharmaceuticals.

For further rules and principles applying to advertising aimed at health-care professionals, please see question 9. Further regulations on additional issues related to the above are laid down in Decree No. 3/2009 of the Minister for Health Care.

In practice, it is important that advertisers register with the National Institute for Quality and Organisational Development in Health Care and that they pay the fees, which may be considerable. In the case of some medications, the advertiser has to prove his or her qualification, the procedure of which is laid out in Act XCVIII of 2006 and Decree No. 3/2009 of the Minister for Health Care.

Please also note that the Health Insurance Supervisory Authority, which was until 15 September 2010 the competent authority of the mentioned registrations, applied a contra legem definition of 'advertisement aimed at health-care professionals'. According to an official opinion dated 2 September 2009, which is contrary to section 5 of Decree No. 3/2009 of the Minister for Health Care, it considered the provision of information that can also be aimed at consumers an advertising activity aimed at health-care professionals if such information is directly transmitted to health-care professionals. This interpretation of the Health Insurance Supervisory Authority was contrary to section 5 of Decree No. 3/2009 of the Minister for Health Care, as information provided to consumers (ie, patients) is not treated as an advertisement aimed at health-care professionals.

Where advertisers provide the aforementioned kind of information without having obtained the necessary permit, they can be fined up to €100,000. This fine can be contested in court, but there is no case law on the matter. It is submitted that the Health Insurance Supervisory Authority interpreted the above-mentioned provision in a very broad way because it tries to force advertisers to obtain a permit and to pay corresponding fees even where they may not be obliged to do so under the aforementioned provision. The fees can be as high as 400,000 forints.

The relevant definition of Decree No. 3/2009 of the Minister for Health Care changed on 1 October 2009 and renders the definition more accurate. However, it is by no means certain that the now competent National Institute for Quality and Organisational Development in Health Care will not follow a similar practice, but relevant case law is not yet available.

5 What are the main rules and principles applying to advertising aimed at the general public?

Act XCVIII of 2006 generally bans the advertising of medical products aimed at the public. The only exceptions are prescription-free medical products and medical aids that are not subject to state subsidies. The Act also lays down not only the compulsory elements of an advertisement (eg, the name of the product, an express invitation to read the information leaflet, the pattern of correct usage) but also specifies what information cannot be given (eg, recommendation by scientists, information that could prompt readers to self-diagnose, guarantees of success).

These provisions, however, do not apply to advertisements containing only the name of the producer of the medicine. Such advertisement may only be made in the form of flashback advertisements (advertising of prescription-free products that refers back to advertisements in the same advertisement block if the previous advertisement complied with the regulations). The ban for advertising prescription-only medicines does not apply to vaccination campaigns and information on related medicines.

6 What are the most common infringements committed by manufacturers with regard to the advertisement rules?

The majority of infringement cases launched by the National Competition Authority are connected with misleading advertising of food supplements. The infringement is usually committed by stating non-proven positive effects or by announcing that the product has the lowest price, the best effects on health or any other statement that is exaggerated.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

Providing information on off-label usage to health-care professionals falls under the scope of advertisement aimed at health-care professionals. Accordingly, the range of information provided may be significantly wider than in the case of consumer-aimed advertisement, but no information may be provided that cannot be supported by research and development. The basic rules of off-label use are laid down in section 25 of Act No. XCV of 2005, while the specific rules are laid down in Decree No. 44/2004 of the Ministry for Health Care, Social Affairs and Family.

According to these rules, off-label use is only allowed with the express individual authorisation of the National Institute for Quality and Organisational Development in Health Care. This authorisation may be gained by submitting a detailed request containing the reasons for and expected effects of the off-label usage. The request must contain evidence that the off-label prescription is likely to cause an augmentation, stabilisation or cure of the patient's state of health. Furthermore, this may only be done if other medication does not make a treatment possible.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the in-patient and outpatient sector?

The regulations are incorporated into the legislation on the advertisement of products, which means that Act XCVIII of 2006 and Decree No. 3/2009 of the Minister for Health Care (on the detailed rules of the promotion of medicinal products and medical devices, the registration of the medical representatives and of the commercial practice related to medicinal products and medical devices), as well as Decree No. 35/2005 (VIII. 26.) of the Minister for Health Care (on the clinical trial and application of correct clinical practices of investigational medicinal products intended for use in humans) are applicable.Generally, there is no material difference between the rules of the collaboration regarding physicians in the in-patient and outpatient sector.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

Section 14 of Act XCVIII of 2006 sets out the main rules governing the collaboration between the pharmaceutical industry and health-care professionals. Pursuant to section 14(1) of this Act, in the course of promotional activities gifts, pecuniary advantages or other material benefits may not be provided, offered or promised to persons authorised to prescribe or supply medicinal products or medical aids, unless they are inexpensive and they are related to the healthcare activity in which the persons with entitlement for the prescription and distribution of medicinal products is engaged. In the course of promotional activities monetary benefits or financial advantage may not be provided, offered or promised in any way or form under any circumstances.

Section 14(2) goes on to provide that entertainment and hospitality functions may be arranged for the promotion of medicinal products and medical aids solely for professional, scientific and educational reasons. The daily amount spent on such entertainment and hospitality functions by promoters of medicinal products and medical sales representatives may not exceed the limit specified in the Act and shall remain subordinate to the main objective of the meeting. Only healthcare professionals and persons engaged in the supply and distribution of medicinal products or medical aids, or both, may be invited to such trade and promotional events and demonstrations.

Any support provided, whether directly or indirectly, for events and programmes for purely professional and scientific purposes shall always be reasonable in scope and remain subordinate to the main scientific objective of the meeting. Only health-care professionals and persons engaged in the supply and distribution of medicinal products or medical aids may be invited to such trade and scientific events. Promotional activities may be carried out during such events and programmes if the promotional activity (eg, a lecture concerning the application of a specific product, demonstration of a specific product, leasing of exhibition space) is clearly distinguished from the trade and scientific programmes. For the aforementioned purposes, it makes no difference whether the promotional activity is performed directly or indirectly.

Section 14(4) provides that persons engaged in health-care or scientific activities may be provided with in-kind support for participating in trade events and training courses. Such support may be provided to cover expenses (such as travel expenses, accommodations, entry fees, etc) arising directly out of or in connection with attending the events.

Support for an event held at a specific location, or for participating in an event connected to a specific location may be provided only if the resources required for the subject-matter of the event or the necessary expertise is available at that location only, or if the costs of staging such event at a location closer to the work places of the participants would be disproportionately higher.

At a place where a trade and scientific event is held for participants authorised to prescribe medicinal products or medical aids, or both, with social security subsidies, support may be provided for any facultative trade or scientific programme connected to the event, or for participating in such events only if it is held during the same time as the main trade and scientific event.

Other specific legislation may contain further provisions with respect to promotional activities, including the regulations pertaining to free product samples and donations that may be provided to persons qualified to prescribe or supply medicinal products or medical aids.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

The most common infringements committed by manufacturers with regard to collaboration with health-care professionals are the violation of the rules on the marketing and promotion of drugs provided by Act XCVIII of 2006.

In certain cases, manufacturers, through the medical representatives of such manufacturers, provide unlawful benefits in consideration for prescribing or otherwise soliciting their products. In some other cases, manufacturers do not enter into a contract with their medical representatives in the prescribed form of contracts, but as research consultants and other types of subcontractor, evading some taxation duties and the yearly state fees to be paid according to the number of the employed medical representatives.

Due to increased control during the past couple of years, the frequency of such violations has significantly decreased.

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

As of November 2011, hardly any patient organisations exist in Hungary; those that do have virtually no political clout and focus mainly on patient treatment and not on mediatory rules between patients and the pharmaceutical industry. The only explicit right that legislation confers on them is their role in the mediatory process between patients and medical institutions (section 6 of Act CXVI of 2000).

12 Are manufacturers' infringements of competition law pursued by national authorities?

Yes. The competent authority is the Hungarian Competition Authority (HCA). The HCA has full jurisdiction in all affairs in connection with the infringement of competition law and is also the competent body to authorise mergers within the sector.

According to Act LVII of 1996 on the Prohibition of Unfair Trading Practices and Unfair Competition (the Competition Act), a dominant position is not sanctioned per se, but only the abuse of it. A company is deemed in a dominant position if it can determine its practices without considering the reactions of other competitors, suppliers or consumers. If a company in such a position pursues activities that, for example, aim to exclude or hinder other competitors, or force other parties to accept unwanted conditions, the HCA will start proceedings against such company.

Restrictive agreements among competitors are also generally forbidden, both horizontally and vertically. Horizontal agreements are those between market players on the same level of the market (eg, two manufacturers), while vertical agreements are those between market players on different levels of the market (eg, a manufacturer and a distributor). Exceptions apply pursuant to article 13 of the Competition Act to agreements of minor importance (where the combined market share of the parties does not exceed 10 per cent) or in the case of companies which are under the same management. The Hungarian government may grant exemptions from these rules by an act of legislation (a governmental decree if, for instance, the agreement is conducive to market development within that particular industry).

Please note that exemptions and exceptions are not the same. Exceptions are statutory derogations from the rule, while exemptions are granted on an ad hoc basis by the Hungarian government by way of governmental decree.

13 Is follow-on private antitrust litigation against manufacturers possible?

According to section 339 of the Hungarian Civil Code, a person causing damage to another person in violation of the law shall be liable for such damage. The injuring party, however, shall not be liable if it can be proven that he or she has acted in a manner that can generally be expected in the given situation. This makes antitrust litigation theoretically possible. However, there has been no known major case in which the pharmaceutical industry was involved.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Yes. Medical devices ('medical aids' in the words of the relevant legislation, which is Act XCVIII of 2006) fall under the same scope as medical products and they are also divided into the same two categories, namely medical aids that can be subject to state subsidies, and medical aids without subsidy. The regulations are identical.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The main framework is laid down in Decree No. 52/2005 of the Minister for Health Care.

16 Which authorities may grant marketing authorisation in your jurisdiction?

Authorisation may be granted by the governmental body for pharmaceuticals (the National Institute for Quality and Organisational Development in Health Care) or, in accordance with Regulation (EC) No. 726/2004, Regulation (EC) No. 1901/2006 or Regulation (EC) No. 1394/2007, by the European Commission.

17 What are the relevant procedures?

The relevant provisions laid down by Decree No. 52/2005 of the Minister for Health Care define one main and three special procedures. The general procedure describes the regulation of medicines in general. The procedures begin with the filing of the request to register a medicine. The request has to contain, among other things, the data of the applicant; the applicant's billing and mail address, components and agents of the medicine; the production technology used; the result of physical-chemical, biological and microbiological, pharmacological, toxicological, preclinical tests, pharmacovigilancy requirements and measures; a draft of the usage label; the packaging, et cetera. National Institute for Quality and Organisational Development in Health Care will then decide on the basis of the available documentation.

Medicines with isotopes require additional documentation. For the authorisation of isotope generators, a detailed description of the system has to be handed in that also describes the quality and composition of the daughter isotopes, as well as qualitative and quantitative descriptions of the eluate or sublimate. Homeopathic and traditional medicines may be subject to a simplified procedure if the label of homeopathic medicines contains no therapeutic advice, they are applied externally or taken orally and their dilution guarantees that they are harmless. Traditional medicines may be subject to the simplified procedure if they have already been used therapeutically for at least 30 years, are applied externally or taken orally and the available information on the medicine is sufficient to guarantee a usage based on tradition.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Yes, pursuant to section 18(7) of Act No. XCV of 2005 the sunset-clause applies after a period of three years, but this process is not automatic, the invalidation lies within the discretion of the National Institute for Quality and Organisational Development in Health Care and requires a resolution on the matter. There is therefore a possibility to request the extension of said deadline pursuant to section 18(8). In such case the holder of the licence may apply for the extension by justifying cases deserving special consideration and for the protection of public health. Furthermore, marketing licences generally expire after five years. A licence can be renewed by submitting a request no later than six months before the expiry date. The competent authority will reassess the risk-benefit balance and, based on its findings, renew the marketing licence for another five years or for an unspecified period.

19 Which medicines may be marketed without authorisation?

All medicines marketed within Hungary must receive an authorisation from the National Institute for Quality and Organisational Development in Health Care or the European Commission. All medicine marketing is conducted within a closed chain that is strictly controlled by the National Institute for Quality and Organisational Development in Health Care and the National Public Help and Medical Officer Service, which is the authority controlling Hungarian GMP (which is a quality standard); it issues the marketing authorisations for medicines and conducts tests on medicines before their wholesale authorisation is granted. The National Public Help and Medical Officer Service is a central, coordinating and supervisory authority responsible for public health. Products marketed as 'products with medical effect' had to be reclassified by 31 March 2011 at the latest if its distributor wished to market them with its effect on health. No product may be marketed as 'product with medical effect' since 1 April 2011. Such products can therefore be classified as either subscription-free or traditional medicine.

20 Are any kinds of named patient (or similar expanded access) programmes in place? If so, what are the requirements for pre-launch access?

Under certain conditions, pre-approval access to medicines is possible. Article 5(1) of Directive 2001/83/EC has been implemented. Therefore, pursuant to section 7 of Act No. XCV of 2005, at the manufacturer's request and if justified by patient care interests deserving special consideration, the National Institute for Quality and Organisational Development in Health Care may grant a provisional marketing authorisation, before all trials are completed in full, for a product that is deemed to be of appropriate quality based on the assessment already completed and where the risk-benefit balance is considered to be favourable for therapeutic value, for a maximum period of one year.

In such cases, the National Institute for Quality and Organisational Development in Health Care lays down the reporting requirements for the marketing authorisation holder pertaining, in particular, to the safety of the product. The conditions set out have to be reported at the times prescribed in the authorisation.

The National Institute for Quality and Organisational Development in Health Care may also temporarily authorise the distribution of an unauthorised medicinal product for the period of one year in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm and hence may present a substantial risk to public health.

A special marketing authorisation for the distribution of an unauthorised medicinal product may also be granted if a medicine

meets most of the criteria, but where the requirements on effectiveness and the risk/benefit ratio are merely suspected and cannot be confirmed since the number of patients involved in the clinical trial of the product is insufficient due to the rarity of the disease.

Compliance with the requirements is assessed at least once a year. At the manufacturer's request the time limit of such provisional marketing authorisation may be extended by a maximum of one year.

Pricing and reimbursement of medicinal products

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

The market price of medicines is not directly regulated, but only the margin of wholesale and retail (for exceptions, please see question 23). Relevant legislation distinguishes between subsidised and unsubsidised medicines. The price of the latter may freely be determined by the reseller. The first category is further divided into: medicines without marketing authorisation, and medicines with marketing authorisation. For the first sub-category, the margin of wholesalers may not be higher than 20 per cent of the import price excluding VAT, while the margin of retailers may not be higher than 40 per cent of the wholesale price. For the second sub-category, the wholesalers' margin gradually decreases from 12 to 5 per cent depending on the product's import price excluding VAT, while the margin for retailers decreases from 26 per cent to 17 per cent of the wholesale price, while being additionally capped at approximately €3.50 per product.

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

No, there is no such obligation. However, medicines are mostly only sold in higher quantities if they are subsidised by the National Health Insurance Fund. As for generic medicines, a new 'blind auctioning system' has been introduced; see question 23.

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

The price of state-subsidised medicines is determined by the manufacturer. The National Health Insurance Fund (NHIF) will, according to principles of price and health-care aims, determine if a product may be subject to state subsidy and specifically determine the amount of state subsidy, which may be proportional (up to 100 per cent) or a fixed amount. The patient will then only have to pay the difference between the manufacturer's price and the state subsidy. The subsidy is directly transferred to the pharmacy, meaning that the patient does not have to apply for reimbursement. The prices are made publicly available in the official paper of the NHIF.

During the issuance of the marketing licence, some medicines are determined to be used only for in-patient treatment. The price of these prescribed medicines is completely refunded by the NHIF. The NHIF will only subsidise medicines to the extent described on the label. In case of off-label prescription, the costs of the medication may only be reimbursed at the discretion of the NHIF.

Furthermore, in 2010, the 'blind auctioning system' has been introduced. In this system, the manufacturers of generic medicines will have to submit blind offers for their generic medicines (ie, without knowledge of the other offers for the same generic agent) while also declaring that they will sell these medicines at the offer price for at least half a year. After completion of the auction, the medicines with the lowest price will receive the maximum amount of subsidy available for that agent, while medicines that are at least 5 per cent more expensive than the reference will only receive a 15 per cent lower state subsidy.

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

The NHIF is the competent authority to decide if a medicine shall be added to the list of medicines receiving state subsidy. The relevant procedure can be initiated by a request submitted on a standard form with the required annexes. Within the procedure, the price of the medicine is determined by the manufacturer, but the NHIF will, based on principles of health-care aims and cost-effectiveness and the procedure described under question 23, determine if the medicine shall receive state subsidy and to what extent. The procedural fees vary between approximately €1,100 and €5,500, depending on the type of procedure and agent. These decisions of the NHIF are published monthly. In consequence, no retailer will be entitled to sell the medicines for a higher price than the price determined in the decision on the acceptance plus the applicable maximum margin described in question 22.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

No. Manufacturers, wholesale and retail distributors do, however, have a payment obligation if they meet certain criteria. Holders of a marketing authorisation of state-subsidised medicines shall, however, pay a contribution amounting to 20 per cent of the quotient of the state subsidy multiplied by the manufacturer's price or import price and the gross retail price. A similar obligation is imposed on pharmacies having a total margin over 10 million forints per fiscal quarter. In such a case, a 'solidarity contribution' between 1.5 per cent and 6 per cent of the margin over 10 million forints shall also be paid. Holders of a wholesale licence shall also pay a contribution of 2.5 per cent of their total wholesale margin.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

If the origin or the composition of a medicine is not in accordance with the labelling, it is considered to be counterfeit. This can mean that the product contains no agent at all, contains it in lower dosage or also contains other agents or products that contain agents not allowed in Hungary, or that the distributor is different from the one indicated on the label.

Every member of the distribution chain must have a valid licence issued either by a Hungarian or another EU member state authority. The National Public Help and Medical Officer Service monitors all legal distribution of medicines from the importation to the final resale. It also supervises pharmacies and commercial resellers allowed to market prescription-free medicines. To suppress the possibility of illegal medicines on the legal market, medicines destined for resale may only be purchased from authorised wholesalers. Online pharmacies may only operate if they operate from a licensed 'real' pharmacy.

27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

Since the promotion of prescription-only medicines is prohibited pursuant to Act XCVIII of 2006, the information available on the subject is very limited. The only information allowed is that such as the product's name, agents used, ATC code and classification (prescription-only, prescription only by specialist, prescription-free, etc).

28 Outline major developments to the regime relating to safety monitoring of medicines.

The regime of pharmacovigilance was already subject to change before the debate started within the European Union. In 2005, the relevant provisions of Act XCV of 2005 on medicinal products for human use and on the amendment of other regulations related to medicinal products have completely reshaped the Hungarian legal background. It has nearly completely abolished Act XXV of 1998 on medical products for human use and is in compliance with the relevant EC legislation. The National Public Help and Medical Officer Service may conduct regular and irregular inspections if side effects are observed.

Holders of marketing authorisation, pharmacists engaged in wholesale or distribution and doctors are obliged to report all noticed quality deficiencies to the competent authority. This authority will then investigate the medicine and take appropriate actions that can be as far-reaching as removing it from the market. Further detailed rules are laid down in Decree No. 52/2005 of the Minister for Health Care.

Update and trends

The Hungarian health-care legislation is subject to constant and recurring changes that mostly concern the financing aspects. The current plans of the Hungarian government involve among others taking hospitals under direct governmental control, while also assuming the debts of these hospitals. Specific plans and a concrete schedule are however not yet publicly available. Further plans involve the reform of the rules on price subsidies of medicines. The complete governmental programme on the reform of the health-care sector is called the 'Semmelweiss Programme'.

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