REGULATION AND COMPETITION IN THE HEALTH PROFESSIONS
HUNGARY
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Structural approaches

- **Quality standards and entry**

1. In Hungary the government establishes through the responsible ministries the standards and the number of training places, such as the possible number of the applicants for the university education, or the authorised training places for each medical practitioner. In our view this entry control does not keep up with the real demand of the market and sometimes certain professions exceed the indicated numbers. However, beyond the obligate educational qualifications, in the case of medical service providers there are not any quantitative limits on the number of practitioners who may enter the profession in a given time period. The eligibility of foreign graduates depends on the diploma and the citizenship of the graduate. If he/she is an European Economic Area (EEA) citizen, having an EEA diploma/certificate falling under the scope of a sectoral directive of the European Council, the diploma/certificate will be recognised without any condition. The diplomas falling under the scope of the general directives are also recognised with the reservation of fulfilling some requirements (exam, adaptation period or additional training). Other than the above-mentioned diplomas are envisaged thoroughly and the holder either has to fulfil certain requirements such as exam, adaptation period or additional training or the diploma is recognised without any further prescription.

- **Exclusive rights**

2. Generally, in the case of medical services there is a de jure exclusivity where the government establishes the requirements of licenses or allowances to practice certain medical procedures, in accordance with the type of treatments or services.

3. In the case of pharmaceutical service providers the only regulation of the access to profession is obtaining a qualification as pharmacist in accordance with the European Council Directive 85/432/EEC coordinating national laws in the field of pharmacy activities. In accordance with the above-mentioned Council Directive (Article 1 .2), pharmacists have access to a set of activities, among which, the “storage; preservation and distribution of medicinal products in pharmacies open to the public”. In line with the principle expressed in the same Directive, the Hungarian authorities have reserved such activities to pharmacists. Finally, the legislation allows some exceptions to the exclusive rights of distribution of medicines for pharmacists in order to meet specific public health needs (veterinarians can dispense veterinary medicines, and in certain cases, when there are no pharmacies in the proximity doctors can dispense medicines).

4. In the area of the pharmaceutical services some changes relevant to entry to the profession have been implemented in Hungarian law as a consequence of the accession to the European Union. This is mainly to ensure that the way the profession is organised is in line with the European Council Directives 85/432/EEC and 85/433/EEC (concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy including measures to facilitate the effective exercise of the

right of establishment). These changes for example the introduction of new provisions to achieve a balance between practical training and courses in the curricula; or the removing of the obligation that once existed to have practiced a certain number of year before been eligible to open and being responsible for a pharmacy.

- **Organizational structure**

5. In Hungary the professional associations don't have any right to limit the organization of their members in the pharmaceutical retailing, however there are considerable limitations both on the structure of pharmaceutical retail industry and on the organizational structure of individual pharmacies through government regulations. The opening of new pharmacies is restricted through the Act LIV of 1994 On the Establishment of Pharmacies and on the rules of their operation. According to this law there are restrictions both on population numbers and geographical distance, resulting in an effective legal barrier to entry to the pharmaceutical retail sector. There are also rules on the corporate form that can be adopted by the pharmacists, and on the number of outlets that can be owned by a pharmacist. Ironically, the pharmacist, who has a personal right to operate in one pharmacy, cannot operate in another at the same time, but the regulations allow business entities to own multiple pharmacies (pharmacy chains).

6. There are no such limitations regarding other health professions.

- **Consumer redress**

7. In Hungary regarding the liability regime a mid-level one is adopted, although there are some aspects that may have relations with the low liability regimes. Since 1989 according to a Directive of the Ministry of Health no private health provider can start it's activity without the appropriate insurance. In addition in accordance with the Act CLIV of 1997 (Health Act) the national health authority, the National Public Health and Chief Medical Officer's Service refuses to give a permission to perform health service for any providers without insurance.

8. Regarding the legislation all physicians must gain a Hungarian Medical Chamber membership in Hungary. Without it, performing any medical services is forbidden. If the possibility of medical errors occurs the Chamber starts an ethical investigation, which - in case of proved malpractice – may lead into revoking the membership. In case of malpractice lawsuits medical experts starts a detailed examination according to Civil Law.

9. As the patients are not well informed or qualified considering their rights and the necessary steps in case of malpractices, there are professionally trained experts who helps consumers for free of charge. These experts have offices inside the hospitals so they are close when in need.

10. In Hungary the medical services are mainly performed as public services. Speaking about the question of the behaviour of professionals it means physicians don't fear of malpractice suits as in those countries that have a high liability regime. This derives from the fact that if any medical malpractice occurs during performing a public service, the liability appears on the level of institute.

- **Market power limitations and competition agencies**

11. In our view, the competition law is applicable to the health services. The Hungarian Competition Authority (Gazdasági Versenyhivatal, hereinafter the GVH) investigated mainly the anticompetitive restrictions of the professional organisations so far.

12. On the one hand, the GVH launched a proceeding[1] against the Hungarian Medical Chamber in 1999 to reveal whether some points of its Code of Conduct were not against the Competition Act. The GVH found that one clause of the Code of Conduct (stating that setting lower price than the recommended price of the Ethical Code qualifies as ethical harm under the Ethical Code) violated the prohibition of restrictive agreement. The GVH again investigated the restrictive conditions of the Code of Conduct of the Hungarian Medical Chamber[2] in 2001-2002 because the Code prohibited the advertisement of medical services and threatened its members with sanctions for the violation of this provision. The GVH found that the general ban on advertisement might have restricted competition among undertakings and also limited the consumers' access to information. The GVH pointed out that these rules of the Code of Conduct were against the general prohibition of agreements and were capable of restricting competition.

13. On the other hand, in the case of the Hungarian Chamber of Pharmacists[3] the Office investigated those points of their Code of Conduct, which defined that their members may not apply lower prices than the minimal prices (set in the Code of Conduct) are. As a result of the investigation they changed the mandatory prices to recommended prices, so that establishing a voluntary compliance, the GVH terminated the proceeding against them. Following this decision, the GVH tried to help them in the preparation of the new Code of Conduct through competition advocacy, however this process was not sufficient, and currently there is an investigation concerning the exemption from the prohibiton of restrictive agreements. (For further details please see the answers for competition advocacy.)

Behavioral approaches

- **Conduct rules**

14. In accordance with EU Directive 83/2001/EC, advertising directly to the public for prescription only medicines and therapeutic aids is forbidden and advertising of non prescription medicines is allowed but subject to certain conditions defined in legislation to address public health concerns. But, the advertising of those products, what the state regulation does not qualify as a therapeutic aim (such as eyeglasses or contact lenses) is allowed.

- **Fee setting, Contractual Mechanisms**

15. In general, the state system of medical payment mechanisms is performance based and determined of the type of services. The National Health Insurance Fund (NHIF) introduces the per capita system for family doctors, a fee-for-service system for out-patient health care services. Hospitals are financed through Diagnosis Related Groups (DRG). Both the NHIF and the Information Centre for Health manage the procedure. In case of chronic in-patient care the number of days spent in hospital is the underlying basis for payments.

16. The benefits in kind for health services provided by the suppliers financed by NHIF and the benefits in cash provided by the NHIF are as follows:

  – **Health services** provided free of charge according to the "in natura" (in kind) principle, like preventive medical examinations, medical care by family physicians (primary health care services), dental care, out-patient care, in-patient care, delivery care, medical rehabilitation, patient transportation, accident health supply.

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1 Case no Vj-137/1999

2 Case no Vj-45/2001

3 Case no Vj-134/1999

- **Cost allowances** to health care services, like drug cost allowance, medical aids cost allowances, travel cost reimbursement, international medical cost reimbursement.

- **Co-payment is charged** in the following instances: orthodontic treatment under the age of 18, tooth keeping and replacement above the age of 18, extra meal and accommodation for in-patients, sanatorium treatment.

- **Benefits in cash** delivered by the Fund are the sick pay, the pregnancy and confinement benefit, the childcare fee, the disability benefits, the accident benefits and the accident pension.

17. Significant **co-payment** by patients is required for certain dental treatments, services rendered without referrals, and services in addition to those ordered by specialists and extra hotel/accommodation costs. Co-payments are also paid for chronic care and treatment in sanatoriums. Medical services covered neither by the NHIF nor by the State are classified as out-of-pocket expenses. Some out-of-pocket payments are on medicines and medical aids. Finally, informal gratitude payments constitute another category of out-of-pocket expenditure.

18. The NHIF finances the recurrent costs in the framework of **contracts** with health care providers. The investment and development costs of the health care institutions do not burden the budget of the Health Insurance Fund. Accordingly, their costs are covered by the owners of the institutions or by the state. The **Ministry of Health has no longer direct responsibility** concerning financing health care services, except high-cost diagnostic procedures, organ transplants and blood supplies. The Ministry of Finance bears responsibility for fiscal policy and budget planning as well as for the macro-economic implications of health care financing.

19. In the **medical services** the professional chamber is binding concrete prices for all kinds of services in the public sector and recommended prices (“indicative fees”) in the private on the basis of state authorisation. In the pharmaceutical services generally the state establishes the margins and fees, where pharmacists are remunerated by the government under a system regulating prices and reimbursement for medicines and prescription fees. However, some pharmacists’ services (not the medicines) are free of charge to the patients.

20. In the case of **medicines**, there exist uniform retail prices in a sense, that for the same drugs there is a same price in every pharmacy. It means, that there is no competition between pharmacies (in other words, there is no intrabrand competition), but there is some competition between drugs of different producers in the same product market (“interbrand competition”).

21. The reason for uniform prices is a combination of margins and government regulations. There is a maximised wholesale margin and a maximised retail margin (based on the wholesale price) for every drug. (There is generally no regulation concerning the producer’s prices.) In addition there is a ministerial regulation, stating that the Hungarian Chamber of Pharmacists quarterly announces the referential retail prices for every drug. This regulation (along with another provision of the Pharmacy Act) is interpreted and operated in such a way, that it leads to the uniform retail prices in Hungary.

22. In accordance with our obligation to harmonize legislation, it has become necessary to transpose European Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (hereinafter: Transparency Directive).

23. Prior to its accession to the EU, Hungary used a completely different reimbursement scheme. The competent authority to decide on including medicinal products in the list of products covered by social insurance was the Government until 2002, and subsequently the Minister. In other words, the price of medicinal products agreed as the basis for public financing and the size or amount of reimbursement were set in the frames of a normative decision-making mechanism.

24. Before taking such decisions, price negotiations took place, which were announced and conducted in accordance with the provisions of legislation, and the outcome of the decisions were also published in a piece of legislation. Therefore no individual legal remedy was available. The application for reimbursement of the individual pharmaceutical manufacturer was published annually, as the outcome of price negotiations, in the relevant pieces of legislation. Anything that was not published in the list had to be construed automatically as rejection.

25. Consequently, the normative decision-making system used previously had to be transformed into individual decisions.

26. In keeping with the aforementioned, legislation was amended in both 2002 and 2003, while the comprehensive harmonisation of the drug reimbursement scheme in keeping with the Transparency Directive, with regard to the detailed definition of the rules of procedures to be followed in decisions on including a medicinal product in the scope of the social insurance system as well as the criteria of including a medicinal product in the list of products covered by the Health Insurance Fund, was accomplished as of May 1, 2004.

27. Finally, In the case of the **medical devices and therapeutic aims** in general, also the state establishes the type and extent of the subsidised product, also the area of those patients who can get them without paying. In addition, the distribution of the medical devices and therapeutic aims are allowed to those retailers who make a contract with the National Health Insurance Fund and fulfil the quality requirements of the related regulation. Custom-made devices are only subsidised if the manufacturer obtains a certification awarded by the competent authority (Office for Authorisation and Administrative Procedures) attesting that he fulfils the requirements set by law. Nevertheless previously the manufacturer has to fulfil to these obligations anyhow (regardless subsidy) otherwise he is not entitled to make such devices for the market.

Examples

Dentistry:

- *Whether hygienists are able to perform and set up their own practice to perform basic teeth cleaning, such as scaling and polishing:* No, they are not able.

- *Whether there is a independent body for reviewing complaints by patient-consumers:* No, there isn’t a special body for the dental services, but according to the general rules the patients can appeal to the Chamber or to the General Inspectorate of Consumer Protection.

- *Whether dentists/hygienists must provide clear guidance on their prices in advance of performing treatment:* Yes, they must.

- *Whether dentists/hygienists can advertise, including prices:* No, they can not.

- *Whether dentists/hygienists have any obligation to tell their patients about publicly paid services that they or others provide:* Yes, they have.

- *Whether there are "indicative" fees published by that government or another body and adhered to by the profession:* There are proposed minimum prices by the professional Chamber, but this practice is under revision upon considerations of the competition law.

For pharmacists, please state:

- *The responsibilities of the pharmaceutical professional association:* f.i. consultancy right in the case of establishment of pharmacies; indicative fees; to allow licensing for practicing; to allow the personal right (ad personam). (There's a compulsory membership for all pharmacists performing professional services.)

- *What restrictions may exist to the movement of pharmacists across borders*: The Chamber can measure the allowance of the personal right for the citizens of the EEA, but there is a (mutual) recognition system for the diplomas of the foreigners.

- *Whether there are limitations on the locations of new pharmacies:* In Hungary establishing of a new pharmacy is allowed per 5000 inhabitant and in a distance of 250 metres from each other.

- *Whether pharmacies must be owned by a pharmacist:* Yes, in special circumstances they must be owned by a pharmacist. In limited partnership companies the general partner should be a pharmacist.

- *Whether medicines can be packaged by non-pharmacists:* The magistral products can be compiled only by pharmacists, but can be packaged by non-pharmacists (pharmaceutical assistants) too, in the pharmacy. In the mass production according to the EU-law a qualified person's responsible for the packaging. The qualified person need not be a pharmacist, but must be high educated as a biologist, chemist, doctor, etc.

- *The extent to which Internet delivery of medicines may serve as a substitute to local pharmacist services:* Because of the low penetration of Internet services in Hungary, Internet delivery wouldn't be an effective substitute to local pharmacist services in Hungary, especially in the rural areas. Beside this there is a major resistance from the professional chambers regarding Internet delivery (and other services, such as home delivery, non-stop pharmacies, etc.), and so far their lobbying activity against the introduction of these services was successful.

Medical device delivery linked to professional qualification

In the area of vision care, please state whether:

- *eyeglasses with pre-prepared corrections can be purchased outside of an eyeglass store*: Yes, they can be.

- *custom eyeglasses can only be prepared after a review by an optometrist. If so, are there time limits on when the review must have occurred?* No, there is not any obligation for reviewing. It is a basic personal condition for every enterprise dealing piece-produced optical medical aids in Hungary to employ an optician (or an optometrist for eye-diagnosis with computer or selling contact lenses).

- *indicative prices are provided by the state for certain frames or other services*? There aren't any indicative prices, but there are subsidised products (subsidies can be only given after diagnosis and indication by a doctor).

- *if indicative prices are provided for certain frames, do some stores display only the "uglier" frames in order to increase sales of private unregulated frames?* We do not have any information about such a practice.

In the area of hearing aids, please state whether:

- *hearing aids can be purchased over the counter*: No, it can not be. Similarly to the optical aids, hearing aids can be sold only in stores employing an audiologist or other qualified staff (acoustic specialist or physiologist).

- *hearing aids must be fitted with the help of an audiologist*: Not required.

- *hearing aids are approved for distribution by a government authority and, if so, whether the approval is contingent upon delivery by audiologists*: All hearing aids which are medical devices must be approved according to the rules of EU-law.

- *there are proven risks of installing modern hearing aids without an audiologist, particularly those designed for self-installation*: We do not have any information about this practice.

Competition advocacy

28. In the course of the regulation of health professional services the competition advocacy activity of the Hungarian Competition Authority proved to be a fairly effective instrument. In the framework of our competition advocacy activity, we usually pronounce against market entry barriers. However, it often happens that those practitioners who work in service sectors where intense competition exists make an effort to put pressure on the government in order to make the market entry more difficult by administrative provisions (like qualification prescriptions, etc.). The GVH is not able to intervene effectively in these new regulations; it has only the possibility to gain information on the regulation practice of health services.

29. The competition advocacy activity of the GVH is generally connected to the liberal professions as a whole, so the GVH tries to intervene on a broader level. The results achieved by the authority are mainly from the pharmaceutical sector, but we used them as a starting point in other areas of the health sector.

30. The general experience of the GVH is that special remedies may be – in the framework of advocacy – to hold discussions with professional bodies, consumer organisations or national regulatory authorities responsible for health professions. For instance, the GVH has contacted the Hungarian Medical Chamber bilaterally. The GVH investigated the restrictive conditions of the Ethical Code of the Chamber[4] in 2001-2002 because the Code prohibited the advertisement of medical services and threatened its members with sanctions for the violation of this provision. The GVH found that the general ban on advertisement might have restricted competition among undertakings and also limited the consumers' access to information. The GVH pointed out that these rules of the Ethical Code were against the general prohibition of agreements and were capable of restricting competition. As a result, the Chamber has to modify its ethical rules; therefore we initiated a discussion in order to help them in the preparation of the regulation of advertising. The aim of this dialogue is that during this consultation process some of the most severe anticompetitive provisions disappear from the proposal. We hope that through this advocacy we will be able to prevent future enforcement proceedings, which nevertheless still stays an option if the Code remains disproportionately anticompetitive.

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4 Case no Vj-45/2001

31. It is also worth mentioning in this context that the GVH has contacted the Hungarian Chamber of Pharmacist, as they are just about to renew their ethical rules, also in order to help them in the preparation of the new Code of Conduct. However, this consultation process was not successful, because the unproportionally anticompetitive provisions have not changed, nevertheless the ex-officio investigation still serves as an option.

32. Another potential item on the GVH's agenda for the near future is to organise a bilateral discussion with the regulators of the health services to justify those types of competition restrictions, which are set up by state regulation and are not proportionate instrument to ensure the quality of services.

33. Finally, the GVH published a booklet on the competition issues in the pharmaceutical sector. This booklet – among other issues – deals extensively with the pharmacies and their regulation, proposes to set up a more procompetitive regulatory framework in pharmaceutical retailing, and includes some kind of general economic analysis and broad conclusions about the possible benefits of competition.