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Utjecaj Europske Unije na stomatološku profesiju

The Influence of the European Union on the Dental Profession

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Sažetak

Europska Unija uređuje područja koja ne mogu regulirati nacionalna zakonodavstva. Već je prihvaćeno nekoliko direktiva o stomatološkoj profesiji, a omogućuju europskim doktorima stomatologije da otvaraju ordinacije i obavljaju usluge u bilo kojoj državi članici. Pritom imaju ista prava i obveze kao i njezini državljani.

Diplome, certifikati i drugi dokazi o školovanju uzajamno se priznaju, kako bi se olakšalo slobodno kretanje unutar Unije. Također postoje i direktive o slobodnom kretanju robe, elektroničkoj trgovini, promidžbi i zahtjevima za stomatološkom izobrazbom na dodiplomskoj ili poslijediplomskoj razini. U ovom tekstu objašnjeni su najvažniji članci svake direktive, a želi li netko podrobnije podatke može pročitati dokumente koji ga zanimaju.

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Adresa za dopisivanje

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Uvod

Najvažnija je zadaća Europske Unije (EU-a) stvoriti zajedničko unutarnje tržište te ga urediti, budući da to ne mogu učiniti države članice pojedinačno (1).

Pet najvažnijih zadataka EU-a jesu: poboljšati gospodarski i socijalni razvoj, promicati Europsku Uniju na međunarodnoj razini, europsko državljanstvo, razvijati Europu kao područje sloboda, sigurnosti i prava te održavati i razvijati europsko zakonodavstvo.

Svaki državljanin neke od članica EU-a mora imati mogućnost da slobodno živi, radi i obavlja usluge u svakom dijelu Unije, s istim obvezama i pravima kao i stanovnici države u koju je došao (sloboda kretanja osoba). Unutarnje tržište također jamči i slobodu kretanja robe i kapitala.

Introduction

The most important goal of the European Union is to create an internal market and to regulate the matters that cannot be handled by the individual member states (1).

The five most important aims of the Union are to promote economic and social progress, to speak for the European Union on the international scene, to introduce European citizenship, to develop Europe as an area of freedom, security and justice and to maintain and build on the established EU Law.

Every citizen of a EU member state must have the possibility of free settlement, to work and to provide services in every part of the Union with the same rights and obligations as the nationals of the receiving state (free movement of persons). Also the free movement of goods and capital in the internal market will be guaranteed.

Europska komisija (EK) prihvatila je strategiju javnog zdravstva o onim pitanjima koja države članice ne mogu riješiti pojedinačno, kao što su prevencija, praćenje i nadzor zaraznih bolesti, borba protiv duhana, sigurnost živežnih namirnica te ostaloga.

EU također uređuje stomatološku profesiju. Doktor stomatologije s priznatom diplomom moraju imati mogućnost rada u cijeloj Uniji. Zato su u direktive uvršteni i uzajamno priznavanje diploma i usporedivi programi dodiplomske i poslijediplomske izobrazbe.

Pravila natjecanja trebala bi jamčiti da unutar zajedničkog tržišta postoji barem najmanji oblik natjecanja, što znači da je dopuštena promidžba donekle i za medicinske profesije.

EU štiti i potrošače (primatelje usluga, op. prev.), regulira edukaciju i vokaljsku naobrazbu te potiče istraživanja i razvoj tehnologije.

Direktiva je dio europskoga zakonodavstva, a odnosi se na države članice. Kada bude prihvaćena na europskoj razini, svaka će država članica morati osigurati da se ona učinkovito uvrsti u njezin pravni sustav. Direktiva određuje konačni rezultat, a oblik i način primjene stvar je svake države članice. Zapravo, ona postaje djelotvorna tek kada se uvrsti u nacionalno zakonodavstvo. No, čak ako država i nije primijenila direktivu, neke od njezinih odredbi mogu imati izravan učinak. To znači da, ako direktiva daje izravna prava pojedincima, tada se oni mogu na nju pozivati na sudu, ne čekajući provedbu u nacionalnom zakonodavstvu. Zatim, smatra li pojedinac da je na gubitku zbog toga što zakonodavac još nije proveo direktivu, on može državu tužiti za štetu. Takve štete mogu nadoknaditi samo nacionalni sudovi (2).

Čitatelji bi trebali proučiti i "EU Manual of dental practice", jer je to trenutačno najdetaljnija knjiga o položaju europskog doktora stomatologije na unutarnjem tržištu.

Direktiva 78/687/EEG (3): stomatološka edukacija

Kako bi se postiglo uzajamno priznavanje diploma, certifikata i drugih dokaza o formalnim kvalifikacijama osoba koje obavljaju stomatološku djelatnost te da im se olakša sloboda pružanja usluga

The commission developed a public health strategy and it deals with health problems that cannot be solved by individual member states alone, such as the prevention, the monitoring and the control of communicable diseases, the combat against drugs and tobacco, food safety and others.

The European Union regulates also the dental profession. Dentists with a recognized diploma must have the possibility to work in the entire Union. Therefore the mutual recognition of diplomas and a comparable program of undergraduate and postgraduate education is laid down in directives.

Rules on competition should guarantee that within the internal market at least a certain form of competition will remain, which means that to a certain extent publicity is allowed, also for the medical professions.

The European Union also protects the consumers in the Union, regulates education and vocational training and stimulates research and technology.

A directive is a part of European legislation, which is addressed to member states. Once such legislation is passed at the European level, each member state must ensure that it is effectively applied in its legal system. The directive prescribes an end result. The form and methods of the application are matters for each member state to decide for itself. In principle, a directive takes effect through implementation on the national legislation. However, it is possible that even where a member state has not yet implemented a directive, some of its provisions could have direct effect. This means that if a directive confers direct rights to individuals, then individuals could rely on the directive before a judge without having to wait for national legislation to implement it. Furthermore, if the individuals feel that losses have been incurred because national authorities failed to implement directives correctly, then they may be able to sue for damages. Such damages can only be obtained in national courts (2).

The reader of this article should consult also the very complete EU Manual on dental practice, which is at this moment the most comprehensive booklet on the position of the European dentist on the internal market.

The Council Directive 78/687/EEG (3): dental education

With the view to achieving the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of dental practitioners and to facilitate the freedom to provide services and

i prava poslovnog nastana, zadaća te Direktive jest uskladiti i usporediti izobrazbu (dodiplomske i specijalističke) te odrediti minimalne zahtjeve, ostavljajući slobodnom organizaciju stomatološke edukacije.

Studenti stomatologije moraju imati znanja o:

- znanostima na kojima se temelji stomatologija te moraju dobro razumjeti znanstvene metode;
- konstituciji, fiziologiji i ponašanju zdravih i bolesnih osoba (u odnosu prema stomatologiji);
- strukturi i funkciji zuba, usta, čeljusti i povezanih tkiva u zdravlju i bolesti;
- kliničkim disciplinama i metodama koje doktoru stomatologije omogućuju sveobuhvatnu sliku anomalija, lezija i bolesti zuba, usta, čeljusti i povezanih tkiva te o prevenciji, dijagnostici i terapiji.

Također moraju imati odgovarajuće kliničko iskustvo pod prikladnim nadzorom kako bi mogli dijagnosticirati, prevenirati i liječiti anomalije i bolesti zuba.

Kompletno učenje mora obuhvatiti najmanje pet godina praktične i teoretske nastave na sveučilištu ili institutu za visoko obrazovanje sa statusom poput sveučilišnoga.

Direktiva državama članicama omogućuje da odobre studij i obavljanje stomatološke profesije (na svojem teritoriju i u skladu sa zakonima i podzakonskim aktima) osobama čije su diplome stečene u državama izvan EU-a.

Da bi se dobio naziv specijalista, potrebno je imati:

- diplomu doktora stomatologije (ili ekvivalentnog zvanja);
- najmanje tri godine studija na sveučilištu;
- dokaz o radu i preuzimanju odgovornosti.

Direktiva određuje sljedeći program studija stomatologije:

- temeljni predmeti: kemija, fizika i biologija;
- medicinsko-biološki predmeti i opći medicinski predmeti: anatomija, embriologija, histologija (uključujući i citologiju), biokemija (ili fiziološka kemija), patološka anatomija, opća patologija, farmakologija, mikrobiologija, higijena, preventivna medicina i epidemiologija, radiologija, fizioterapija, opća kirurgija, opća medicina (uključujući i pedijatriju), otorinolaringologija, dermatovenerologija, opća psihologija – psihopatologija – neuropatologija, anesteziologija;
- predmeti izravno vezani za stomatologiju: protetika, dentalni materijali i oprema, konzerva-

the right of establishment, the coordination and a comparable nature of the training courses (undergraduate and specialty) with the requirement that minimum standards be observed (leaving the organization of the dental education free for each member state) is the purpose of this directive.

Dental students must acquire an adequate knowledge of:

- sciences on which dentistry is based and a good understanding of scientific methods
- the constitution, physiology and behavior of healthy and sick persons (related to dentistry)
- the structure and function of the teeth, mouth, jaws and associated tissues, both healthy and diseased
- clinical disciplines and methods providing the dentist with a coherent picture of anomalies, lesions and diseases of the teeth, mouth, jaws and associated tissues and of preventive, diagnostic and therapeutic dentistry

They also must acquire a suitable clinical experience under appropriate supervision in order to be able to diagnose, prevent and treat dental anomalies and diseases.

A complete period of training includes at least a five-year full time course of practical and theoretical instruction in a university or in a higher-education institute recognized as having the equivalent status.

The directive gives the member states the possibility to allow entrance to the studies of dentistry and to the profession (on its territory and according to its own legal rules) to persons whose diplomas are not issued in a member state of the European Union.

To acquire the title of a specialist the following requirements are necessary:

- a diploma of general practitioner in dentistry
- a minimum training period of three full years of practical and theoretical training in a university
- participate personally in the activities of the establishment and take the responsibilities.

This directive imposes the following programme of studies leading to a diploma in dentistry:

- Basic subjects: chemistry, physics and biology
- Medico-biological subjects and general medical subjects: Anatomy, embryology, histology (including cytology), physiology, biochemistry (or physiological chemistry), pathological anatomy, general pathology, pharmacology, microbiology, hygiene, preventive medicine and epidemiology, radiology, physiotherapy, general surgery, general medicine (including pediatrics), oto-rhino-laryngology, dermato-venereology, general psy-

tivna stomatologija, preventivna stomatologija, anestezija i sedacija u stomatologiji, specijalna kirurgija, specijalna patologija, klinička praksa, pedodontologija, ortodontologija, parodontologija, dentalna radiologija, dentalna okluzija i funkcija čeljusti, profesionalna organizacija, etika i legislativa te socijalni aspekti stomatologije.

Bolonjski dogovori (4)

Svrha Bolonjskog dogovora je:

- prilagodba sustava jednostavno čitljivih i usporednih stupnjeva;
- prilagodba sustava na temelju dva glavna ciklusa - dodiplomskom (bakalaureat) i poslijediplomskom (magisterij i/ili doktorat);
- uspostava sustava kredita zbog promocije najveće mobilnosti studenata i izobrazbe tijekom cijelog života;
- promocija mobilnosti uklanjanjem prepreka za učinkovito slobodno kretanje studenata, predavača, istraživača i administrativnog osoblja;
- promocija europske suradnje u jamčenju kvalitete;
- promocija potrebne europske dimenzije visokog obrazovanja.

Iako to nije prijedlog EU-a nego rektora europskih sveučilišta, taj su dogovor potpisali ministri obrazovanja 40 država. Dogovor je dobro prihvaćen u Europi te ga EU podupire, budući da u različitim zemljama promiče jednobrazni sustav edukacije.

Direktiva 78/686/EEG (5): diplome

Jednakost i uzajamno priznavanje diploma u stomatologiji u EU-u

Svaka država članica priznaje diplome, certifikate i druge dokaze o formalnoj edukaciji u stomatologiji koje državljanima država članica dodjeljuju druge države članice i to tako da im se daju kvalifikacije koje im omogućuju da na njihovu teritoriju obavljaju stomatološku djelatnost na način kao i na području države koja je kvalifikaciju dodijelila. Isto vrijedi i za specijalizacije iz oralne kirurgije i ortodontije.

Ako državljanin neke članice EU-a želi diplomu koja se ne dodjeljuje u državi iz koje potječe, dr-

chology – psychopathology – neuropathology, anesthetics.

- Subjects directly related to dentistry: Prosthodontics, dental materials and equipment, conservative dentistry, preventive dentistry, anesthetics and sedation in dentistry, special surgery, special pathology, clinical practice, pedodontics, orthodontics, periodontics, dental radiology, dental occlusion and function of the jaw, professional organization, ethics and legislation and social aspects of dentistry.

The Bologna agreements (4)

The objectives of the Bologna agreement are:

- adoption of a system of easily readable and comparable degrees
- adoption of a system essentially based on two main cycles, undergraduate (bachelor degree) and postgraduate (master and/or doctorate degree)
- establishment of a system of credits to promote the most widespread student mobility and life-long learning
- promotion of mobility by overcoming obstacles to the effective exercise of free movement for students, teachers, researchers and administrative staff
- promotion of European co-operation in quality assurance
- promotion of the necessary European dimensions in higher education

Although it is not an initiative from the European Union but from the Rectors of the European Universities, the agreements signed by the Ministers of Education of now 40 different countries, is well received in Europe and it has the blessing of the EU since it promotes a uniform system of education in the different countries.

Council Directive 78/686/EEH (5): diplomas

Equivalency and the mutual recognition of diplomas in dentistry in the EU

Each member state recognizes the diplomas, certificates and other evidence of formal qualifications in dentistry awarded to nationals of member states by the other member states by giving such qualifications, as far as the right to take up and pursue the activities of a dental practitioner is concerned, the same effect in its territory as those which the member state itself awards. The same is valid for the specialties in orthodontics and oral surgery.

If a national of a member state of the EU wants to acquire a diploma, which are not awarded in his

žava u kojoj traži diplomu može zatražiti da ispunni posebne zahtjeve regulirane njezinim zakonima, odredbama ili administrativnim odlukama a tiču se te diplome. Država u koju dolazi uzet će u cijelosti ili djelomice u obzir diplomu, profesionalno iskustvo te dodatnu i trajnu izobrazbu koju donosi sa sobom. Mjerodavno tijelo zemlje primateljice tada će odrediti koliko dugo treba trajati posebna izobrazba i kakav će biti njezin program. Odluke će se kandidatu priopćiti tijekom četiri mjeseca od predavanja zamolbe.

Direktiva također priznaje stečena prava. Ako diplome, certifikati i druge titule ne odgovaraju minimalnim zahtjevima edukacije, kandidat će morati priložiti potvrdu iz zemlje iz koje dolazi o tome da je prije izdavanja potvrde najmanje tri godine bez prekida obavljao djelatnost.

Za specijalista se u potvrdi mora istaknuti da je radio kao specijalist u određenom području u razdoblju jednakom najmanje dvostrukom trajanju edukacije koja je predviđena u državi članici te u razdoblju jednakom minimalnom trajanju edukacije iz Direktive 78/687/EEG.

Direktiva predviđa priznavanje diploma doktora stomatologije i specijalista dodijeljenih državljanima EU-a koji su diplomirali u državama izvan EU-a. To je slučaj s državljanima bivše Njemačke Demokratske Republike (NjDR), Litve, Letonije, Estonije (koji su diplomirali u Rusiji) te s državljanima Slovenije (za diplome stečene u bivšoj Jugoslaviji).

Kako se ta odredba može usporediti sa stanjem u Hrvatskoj, detaljnije ćemo ju objasniti. Diplome stečene u Jugoslaviji (prije 25. lipnja 1991. za slovenske državljane) te diplome studenata stomatologije koji su počeli studirati u Jugoslaviji prije toga datuma, priznaju se u Sloveniji kao ekvivalent diploma Republike Slovenije, ali uz uvjet da slovensko mjerodavno tijelo potvrdi da je pojedinac obavljao stomatološku djelatnost najmanje tri do pet godina prije izdavanja potvrde.

Pravo poslovnog nastana

Traži li zemlja primateljica potvrdu o fizičkom i mentalnom zdravlju, bit će dovoljna potvrda mjerodavnog tijela zemlje iz koje pojedinac dolazi o to-

own member state, may be required by a host member state to fulfill the conditions of training laid down in respect of the specialty by its own laws, regulations or administrative provisions. The host member state shall, however, take into account, in whole or in part with the diplomas awarded by the member state of the candidate, with professional experience, extra training and continuing education. The competent authorities of the receiving member state will then determine the duration of the specialist education and the program to be followed. Their conclusions will be presented to the candidate within a period of four months after the application.

The directive also recognizes acquired rights. When diplomas, certificates and other titles do not respond to the minimum requirements of training, it will be sufficient that the applicator delivers a declaration of the authorities of the member state of origin that he was effectively practicing for at least three years in the period of five years before delivery of the declaration.

For specialist the declaration has to state that he was practicing as a specialist in that field for a period that equals minimally two times the difference in education foreseen in the member state of origin and the minimum education period foreseen in the directive 78/687/EEG.

The directive foresees in the equivalence of the diplomas of dentist and specialist, awarded to citizens of the EU, who graduated in countries outside the European Union:

That is the case for residents of the former Democratic Republic of Germany (DDR), Lithuania, Latvia and Estonia (who received their education in Russia) and for Slovenia (diplomas awarded by the former Yugoslavian government).

This may be comparable to the situation in Croatia and therefore we will explain this more in detail. Diplomas awarded in Yugoslavia (before 25 June 1991 – for Slovenian citizens) or for students in dentistry whose education in Yugoslavia started before that date, are recognized as sufficient proof on condition that the Slovenian authorities recognize them as equal to their own diplomas and that the Slovenian authorities add a declaration that they have been effectively practicing at least three of the five years before the declaration was delivered.

Right of establishment

If the receiving member state demands a certificate of physical and mental health, a written declaration of the authorities of his member state of ori-

me da ispunjava uvjete za obavljanje stomatološke djelatnosti.

Traži li zemlja primateljica dokaz o uzornom ponašanju, a zemlja iz koje pojedinac dolazi to ne zahtijeva, potreban je izvod iz sudskog registra ili ekvivalentnog registra koji izdaje mjerodavno tijelo.

Zna li zemlja primateljica za neki događaj prije nego što se pojedinac nastanio na njezinu teritoriju, ona može obavijestiti zemlju iz koje pojedinac dolazi te se taj događaj može pobliže istražiti, ali u tajnosti.

Disciplinske, administrativne ili kriminalističke sankcije u odnosu prema stomatološkoj profesiji moraju se proslijediti zemlji primateljici.

Polaže li se u zemlji primateljici zakletva ili postoji neki drugi oblik izjave te ako nju ne mogu obaviti državljani drugih članica, ta će zemlja članica osigurati da se državljanima drugih članica ponudi isti oblik zakletve ili deklaracije.

Postupak autorizacije osobe da počne obavljati stomatološku djelatnost mora biti završen što je prije moguće, a najkasnije tri mjeseca nakon što preda sve potrebne dokumente (osim u slučajevima žalbi).

Sloboda obavljanja usluga

Zemlje članice mogu zahtijevati da se doktori stomatologije (uključujući i specijaliste) učlane u profesionalnu organizaciju ili društvo, prije nego što počnu obavljati djelatnost u toj državi. U slučaju pružanja usluga, što znači privremenost, oni mogu biti iznimke. Osoba koja obavlja uslugu ima ista prava i obveze kao i državljani te države članice, posebice u vezi s pravilima o profesionalnom ponašanju i onima administrativne prirode.

Države članice mogu odrediti automatsku registraciju pod uvjetom da ona ne odgađa ili ne komplicira obavljanje usluga i ne uzrokuje dodatne troškove osobi koja želi obavljati usluge. Zemlja primateljica može tražiti da pojedinac da izjavu mjerodavnom tijelu u vezi s obavljanjem usluga, ako odobravaju privremeni boravak na njihovu teritoriju - u hitnim slučajevima takva se izjava može dati neposredno nakon što je usluga obavljena.

Potrebni dokumenti su izjava da će se obaviti usluga, izjava da određena osoba ima potrebnu di-

gin, proving that he fulfills these requirements, will do.

If the receiving member state demands proof of good character and good repute, and the member state of origin does not, an extract of the judicial record or an equivalent record issued by a competent authority of the member state of origin is necessary.

If the receiving member state has detailed knowledge of a serious matter which has occurred prior to the establishment of the person concerned in that state outside its territory and which is likely to affect the taking up within its territory of the activity as a dentist, it may inform the member state of origin or the member state from which the foreign national comes and demand for an investigation into the facts of the case. That investigation is secret.

Disciplinary, administrative or criminal sanctions in relation with the dental profession shall be made known to the receiving member state.

If a member state requires an oath or any other solemn declaration, and if that cannot be used by nationals of other member states, that member state shall ensure that an appropriate and equivalent form of oath or declaration is offered to the person concerned.

The procedure for authorizing the person concerned to take up the activity of dentistry in a member state must be completed as soon as possible and not later than three months after the presentation of all the necessary documents (except in cases of appeal).

Freedom to provide services

Member states can demand that dentists and specialists in dentistry must be registered or become a member of a professional organization or an Order before they can practice in the member state. In case of the provision of services, which is temporary, they can be exempted from that duty. The person who provides services shall be subjected to the same rights and obligations, and in particular to the same rules of conduct of professional and administrative nature as the nationals of that member state.

Member states may foresee in an automatic temporary registration, provided that such registration does not delay or complicate the provision of services or impose any additional costs on that person. The receiving member state may require the person concerned to make a prior declaration to the competent authorities concerning the provision of services where they involve a temporary stay in its territory; in urgencies this declaration may be made as soon as possible after the services have been provided.

plomu te da obavlja stomatološku djelatnost u skladu sa zakonom u zemlji u kojoj ima prebivalište. Ti dokumenti ne smiju biti stariji od dvanaest mjeseci.

Države članice koje doktoru stomatologije ili specijalistu potpuno ili djelomice zabrane stomatološku djelatnost, osigurat će i privremeno ili trajno oduzimanje diplome.

Postoji li obveza registracije kod javnog tijela zbog osiguranja u vezi s obavljanjem usluga osobama sa socijalnim osiguranjem, pružatelji usluga iz drugih zemalja mogu biti izuzeti od te obveze.

Države članice poduzet će potrebne mjere kako bi osobama iz drugih zemalja članica omogućile dostupnost informacija u vezi sa zakonima o zdravstvenom i socijalnom osiguranju te profesionalnoj etici.

Države članice pobrinut će se - tamo gdje je to moguće - da osobe u vlastitu interesu te u interesu njihovih pacijenata, svladaju jezik kako bi mogle obavljati djelatnost u određenoj zemlji članici.

Uporaba akademske titule

Države primateljice osigurat će da državljani drugih zemalja članica imaju pravo koristiti se akademskim titulama u punom ili skraćenom obliku te na jeziku države članice u kojoj su taj naziv i stekli. Ako se akademska titula može zamijeniti nekom za koju je potrebna dodatna izobrazba (a pojedinac ju nema) u državi primateljici, od pojedinca se može tražiti da se koristi drugačijim nazivom.

Ako je u državi primateljici uporaba profesionalnih titula ograničena pravilima, tada svi državljani drugih zemalja članica moraju rabiti nazive zemlje primateljice.

Direktiva 93/42/EEC (6) i direktiva 90/385/EEC (7) o medicinskim napravama i medicinskim implantatima

Svrha tih direktiva je uskladiti uvjete za sigurnost i zaštitu zdravlja pacijenata s obzirom na uporabu medicinskih naprava, a kako bi se osigurao slobodan promet tih naprava unutar zajedničkog tržišta.

Medicinska naprava je "svaki instrument, aparat, naprava, materijal ili druga stvar koja se koristi sama ili u kombinaciji, uključujući i potreban softwa-

The required documents are a declaration that the service will be provided, a declaration that the person concerned holds the necessary diploma and that he is lawfully practicing dentistry in the member state where he is established. These documents may not be older than twelve months after their date of issue.

Member states which deprive a dentist or a specialist, in whole or in part, of the right to pursue the practice of dentistry, shall ensure the temporary or permanent withdrawal of the diploma.

If a duty exists to be registered with a public social body for the settlement with insurance bodies of accounts relating to the services rendered to persons under social security schemes, shall exempt the service providers from another member state of this duty.

Member states shall take the necessary measures to enable persons concerned to get information on the health and social security laws and on the professional ethics of the host member state.

Member states shall see to it that, where applicable, the concerned persons shall acquire, in their own interests and that of their patients, the linguistic knowledge necessary for the exercise of their profession in the host member state.

The Use of the academic title

Host member states shall ensure that the nationals of member states have the right to use the lawful academic title in so far as it is not identical with their professional title or the abbreviation thereof, of the member state of origin or where they come from, in the language of that state. If this academic title can be confused with a title requiring additional training (that he has not acquired) in the host member state they may be asked to use a title in different wording.

If, however, in the host member state the use of the professional title is subjected to rules, then all nationals of other member states shall use the professional titles of the host member state.

Council Directive 93/42/EEC (6) and Council Directive 90/385/EEC (7) on Medical Devices and Implantable Medical Devices

The purpose of these directives is to harmonize the provisions for the safety and health protection of patients with regard to the use of medical devices in order to guarantee the free movement of such devices on the internal market.

A medical device is "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary

re, a proizvođač ju je namijenio za uporabu na ljudima ili u svrhu:

- dijagnostike, prevencije, praćenja, liječenja ili slabljenja bolesti;
- dijagnostike, praćenja, liječenja ili slabljenja ili kao nadomjestak nakon ozljede ili invalidnosti;
- istraživanja, nadomještanja ili modifikacije anatomije ili fiziološkog procesa;
- kontrole začeća,

te koja svoje primarno djelovanje ne postiže u ljudskom tijelu ili na njemu farmakološkim, imunološkim ili metaboličkim djelovanjem, ali može mu pomoći takvo djelovanje”.

Direktiva određuje uvjete oblikovanja, izrade i pakiranja naprava, osniva Vijeće o standardima i tehničkim odredbama, opisuje usklađenost postupaka koji se trebaju provoditi, pravila o dodjeljivanju oznake “CE” te druge odredbe i postupke u vezi s medicinskim napravama.

Mnogobrojne stomatološke naprave i dentalni materijali koji se koriste u ordinacijama u sklopu su te Direktive, uključujući i izrađene naprave (proteze, krunice i mostove, inlayje, onlayje) te implantate (dentalne implantate).

Medicinske naprave klasificirane su u četiri skupine: I, IIa, IIb i III.

Stomatološke naprave kao što su mobilni i fiksni nadomjestci te implantati uvršteni su u skupinu IIa.

Stomatološke protetske naprave nazivaju se individualno izrađene naprave - svaka je napravljena specifično u skladu s odredbama kvalificiranog medicinskog (stomatološkog) profesionalca koji pod punom odgovornošću određuje njezine karakteristike, a namijenjena je za uporabu samo određenom pacijentu. Dentalni se implantati pak ubrajaju među medicinske usatke (naprave koje se stavljaju u ljudsko tijelo kirurškim postupkom).

Aneks VIII. te Direktive važan je za doktore stomatologije. Za individualno napravljene naprave proizvođač ili njegov zastupnik moraju sastaviti izjavu koja sadržava sljedeće:

- datum odobrenja identifikacije naprave;
- izjavu da je namijenjena isključivo za uporabu određenom pacijentu;
- ime doktora ili druge ovlaštene osobe koja je napisala nalog/odredbu;
- određene karakteristike naprave prema specifikaciji u nalogu/odredbi;
- izjavu da je naprava u skladu s osnovnim uvjetima navedenima u Aneksu I. (sigurnost, usklađenost sa standardima, odabir materijala i kompatibilnost s ljudskim organizmom).

for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.”

The directive lays down the requirements of designing, manufacturing and packaging of the devices, it establishes a committee on standards and technical regulations, it describes the conformity assessment procedures to be followed, the CE marking rules and other regulations and procedures in connection with medical devices.

A lot of dental apparatuses and dental materials that we use in the dental clinic will be handled according to these directives, including the custom-made devices (dentures, crowns and bridges, inlays, onlays) and the implantable devices (dental implants).

The medical devices are classified in four different classes: I, IIa, IIb and III.

Dental medical devices such as removable and fixed dentures and dental implants are in Class IIa.

Prosthetic dental devices are called custom-made devices (any device specifically made in accordance with a duly qualified medical (dental) practitioner’s prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient), whilst dental implants belong to the implantable devices (device which is intended to be totally introduced in the human body by surgical intervention).

Annex VIII of this directive is important to dentists. For custom-made devices the manufacturer or his authorized representative must draw up a statement containing the following:

- data allowing the identification of the device
- a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient
- the name of the medical practitioner or other authorized person who made out the prescription
- the particular features of the device as specified in the relevant medical prescription
- a statement that the device in question conforms to the essential requirements laid down in annex I (safe-

Proizvođač mora čuvati svu dokumentaciju koja omogućuje ovlaštenome državnom tijelu razumijevanje dizajna, izrade i karakteristika proizvoda. Ta se dokumentacija mora arhivirati najmanje pet godina.

Direktiva 95/46/EEC o zaštiti osobnih podataka (8)

Osobni podaci (ime, adresa, institucija u kojoj radi, telefonski broj, elektronička adresa, dob, spol) svaki se dan prikupljaju na različitim mjestima i na različite načine. Doktor stomatologije otvorit će pacijentu karton kako bi mogao odlagati podatke o njemu. Ti se podaci mogu koristiti i za druge svrhe te se mogu razmjenjivati s drugim pravnim ili fizičkim osobama (npr. osiguravajuće kuće). Da bi se ipak zaštitila, Europska je Unija prihvatila Direktivu o zaštiti podataka. Kontrolor podataka je osoba ili tijelo koji obrađuje podatke (to uključuje i doktora stomatologije). Direktiva kaže da je potrebno poštovati neka načela: podaci se moraju obrađivati pošteno i u skladu sa zakonom – potreban je pristanak, moraju se prikupljati za opravdanu svrhu, moraju biti relevantni i ne suvišni (proporcionalnost), moraju se obnavljati i biti točni, a pojedinac mora imati pravo provjeriti njihov sadržaj te ih ispraviti ako su netočni (transparentnost).

Svaka država članica mora osnovati mjerodavno tijelo koje će nadzirati provedbu Direktive te ustanoviti registar s imenima svih kontrolora podataka te vrste obrada koje obavljaju.

Direktiva 2000/31/EC o određenim pravnim aspektima usluga informatičkog društva, posebice elektroničke trgovine na zajedničkom unutarnjem tržištu (9)

Ta Direktiva određuje opći okvir za pravne aspekte elektroničkog trgovanja na unutarnjem tržištu te osigurava slobodni protok informatičkih usluga između država članica. Direktiva mora osigurati visoku razinu zaštite u pitanjima od općeg interesa, posebice u zaštiti maloljetnika i ljudskog dostojanstva, zaštiti potrošača i zaštiti javnog zdravlja. Ona je u skladu s drugim direktivama, kao što su Direktiva o sumnjivom i usporednom reklamiranju (84/450/EEC od 10. rujna 1984.), Direktiva o općoj sigurnosti proizvoda (92/59/EEC od 29. lip-

ty, conformity with the standards, choice of materials and their compatibility with the human body)

The manufacturer must keep all documentation allowing an understanding of the design, manufacture and performances of the product for the competent national authorities. That information must be kept for a period of at least five years.

Directive 95/46/EC on the protection of personal data (8)

Personal data (such as name, address, occupation, telephone number, E-mail address, age, gender) are collected at different places and used in different ways in daily life. A dentist will set up a patient file, collecting data about his patient. These data can be used for other purposes or shared with other parties (insurance company or sick fund). To protect the transfers and the use of these data, the EU has issued this directive on data protection.

A data controller is someone or some entity that processes data (and that includes dentists).

The directive states that some principles should be followed: the data must be processed fairly and lawfully – consent necessary, be collected for explicit and legitimate purposes, be relevant and not excessive in relation to the purpose for which they are processed (proportionality), kept up to date and be accurate and the data subject must have the possibility to check the content of the data and to have them corrected if necessary (transparency).

Each member state must establish an authority that can supervise the applications of the directive and they shall maintain a public register with the names of all data controllers and the type of processing that they perform.

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (9)

This directive lays down a general framework to cover legal aspects of electronic commerce in the internal market and to ensure the free movement of information society services between member states. The directive must ensure a high level of protection of objectives of general interest, in particular the protection of minors and human dignity, consumer protection and the protection of public health. It is in line with other directives such as the directives on misleading and comparative advertising (84/450/EEC – 10/9/1984), on general product safety (92/59/EEC – 29/6/1992), on the approximation of the laws, regulations and admin-

nja 1992.), Direktiva o procjeni zakona, odredaba i administrativnim uvjetima u pitanju s neispravnim proizvodima (85/374/EEC od 25. srpnja 1985.) te Direktiva o promidžbi medicinskih proizvoda (92/28/EEC od 31. ožujka 1992.).

Da bi se uklonile granice razvoju prekograničnih usluga unutar Unije koje osobe reguliranih profesija mogu nuditi na internetskim stranicama, potrebno je da se suradnja osigura na razini EU-a – moraju se prihvatiti profesionalna pravila kako bi se zaštitili potrošači i javno zdravlje. Pravila ponašanja na razini Unije trebala bi biti uzor za određivanje pravila o profesionalnoj etici u komercijalnom komuniciranju i stvaranju prilagodbi, ako se ta pravila poštuju.

Države članice mogu zadržati restrikcije u uporabi elektroničkih ugovaranja s obzirom na to da ugovori prema zakonu traže uključivanje sudova, javnih službi ili profesionalaca s javnim ovlastima.

EU Dental Liaison Committee (10) predložio je Pravila ponašanja (Code of conduct) i ona su sastavni dio Općih načela stomatoloških profesionalnih etičkih pravila za zemlje EU-a. Stomatološke web-stranice moraju imati sljedeće informacije o pružatelju usluga: ime, adresu, elektroničku adresu i telefonski broj (i/ili broj telefaksa), profesionalnu titulu, licenciju i informacije o registraciji.

Ako se nude profesionalne informacije, one moraju biti točne, poštene i pristojne. Sadržaj se ne smije uspoređivati ili navoditi na krivi trag. Informacija mora biti istinita, objektivna, jasna i u skladu s nacionalnim pravom i pravilima ponašanja zemlje u kojoj doktor stomatologije ima ordinaciju.

Doktor stomatologije mora imati osjećaj za profesionalnost i dostojanstvo profesije, ako otvara svoju web-stranicu ili ima elektroničku adresu.

Na stranicama mora biti napisano kada su učinjene posljednje promjene podataka na stranici.

Obvezne informacije uključuju pristanak ili suglasnost bilo kojega osiguravajućeg društva, državnog osiguranja ili neke druge vrste osiguranja, ako se ti podaci navode.

Može se napisati vrijeme kada ordinacija radi i kada se sa stomatologom može razgovarati telefonski ili osobno, zatim detalji o hitnoj pomoći, linkovi prema profesionalnim udruženjima te informacije koje dopuštaju pravila profesije u zemlji u kojoj doktor stomatologije ima ordinaciju.

Ta Pravila ponašanja prijedlog su Vijeća europskih stomatologa (CED-a) te su ih prihvatila sva nacionalna stomatološka udruženja država članica CED-a (Council of European Dentists). Pravila ponašanja etički su, a ne pravni skup pravila.

Administrative provisions concerning liability for defective products (85/374/EEC – 25/7/1985) and on the advertising of medicinal products (92/28/EEC – 31/3/1992)

In order to remove barriers to the development of cross-border services within the Community which members of the regulated professions might offer on the Internet, it is necessary that compliance be guaranteed at Community level with professional rules aiming, in particular, to protect consumers or public health. Codes of conduct at Community level would be the best means of determining the rules of professional ethics applicable to commercial communication and the drawing-up or the adaptation of such rules is encouraged.

Member states may maintain restrictions for the use of electronic contracts with regard to contracts requiring by law the involvement of courts, public authorities or professions exercising public authority.

The EU Dental Liaison Committee (10) produced a Code of conduct, which is an integral part of the General Principles for a Dental Professional Ethical Code in the Countries of the EU.

A dental website must show the following information about the information service provider: his name and address, E-mail address and telephone number (and/or fax), his professional title, license and registration information.

If he provides professional information he must show truthfulness, fairness and dignity. The contents may not be comparative or misleading of skills. The information must be honest, objective, easy to identify and in accordance to national legislation and the code of conduct in the member state where the dentist is established.

A dentist must have regard to professional propriety and the dignity of the profession when establishing a name for his website or E-mail address.

The relevant pages must show the date of the last modification of the page.

Compulsory information is the admission or acceptance policy to any sick fund, national health service or insurance scheme, if available.

May be shown, the hours during which the practice may be accessed by telephone or personal visit, details of urgent and emergency care, a link to a professional association and information that is permitted by the professional rules of the country where the dentist is established.

This Code of conduct is a proposition of the Council of European Dentists and accepted as such by all the national dental societies that are members of the CED. The code of conduct must be seen as an ethical and not as a legal set of rules.

Abstract

The European Union regulates matters that cannot be covered by individual member states. Several directives regulate the profession of dentistry in order to give each European dentist the possibility to establish a dental practice and to provide services in any member state of the Union with the same rights and obligations as the nationals of that member state. The diplomas, certificates and other evidence of formal qualifications are mutually recognized in order to facilitate this free movement of dentists within the Union. Also the free movements of goods, e-commerce, advertising and the requirements of dental education at undergraduate or postgraduate level are guaranteed in other directives. The most important articles of each directive that have an influence on dentistry are explained further and the reader shall consult the directives if he wants to have a more detailed insight.

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