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**The proposal for a Directive on Services
in the Internal Market
applied to Healthcare Services**

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The Commission Proposal for a Directive on Services in the Internal Market is applicable in its entirety to healthcare services just as to any other economic service. The potential impact of the proposal for a Directive on national healthcare systems thus goes far beyond its Art. 23, the article that concerns the assumption of healthcare costs for care received in another Member State. However, some specific features of healthcare make the application of this Commission proposal for a Directive to healthcare services highly problematic. These stem from substantial differences between services within the healthcare sector and services within a purely commercial market.

Why is regulation in the healthcare sector important?

The underlying concept of the proposal is a simple relationship between a consumer and a provider. However, in the healthcare sector not only customers and suppliers operate, but also a “third party”, which pays the major part of the bill. Consequently price mechanisms, based on the relationship between supply and demand, do not function properly. Therefore, healthcare financiers make (contractual) agreements with care providers on the price, content and volume of the care provided to their clients. These contracts should avoid “provider induced demand” and provider induced “moral hazard”. “Provider induced demand” refers to the possibility that care providers, mainly prescribing doctors, steer the demand for care in their own interest. “Moral hazard” indicates the phenomenon whereby more or more expensive medical services than needed are used, due to the fact that not the patient but the financier bears (a part of) the costs. Some economists believe that 'moral hazard' is one of the major causes for upward pressure on healthcare expenditure. It should be noted that not only healthcare financiers that operate with public money enter into contractual relationships with healthcare providers, but private health insurers also try to control their expenditure in this way. Health insurers in the US increasingly apply instruments of managed care to steer the care process. These instruments include selective contracting with providers, the establishment of practice profiles for medical doctors, referral systems, guidelines and standards for medical care. Selective contracting implies that care provided for by non-preferred providers is only partially reimbursed or not at all.

Another specific feature of the healthcare sector is the information asymmetry between patients and healthcare providers. Healthcare is increasingly complex and patients do not have access to all the necessary information; in general they lack the necessary background knowledge to make an informed decision about the care they need and the quality and effectiveness of the service they receive. According to fundamental economic theory, this makes it impossible to achieve an efficient market for healthcare. Since healthcare providers may have other interests than their patients, the information asymmetry makes the relationship very precarious. As it is difficult for patients to assess their own needs properly and in time, public authorities have to provide these guarantees.

Furthermore, in Europe access to high quality healthcare is considered as a fundamental right. European healthcare systems are therefore based on principles of social solidarity and universal coverage and are embedded in social protection systems. The provision of high quality care equally accessible to all citizens is considered a core task of the public authorities. In order to be able to provide these guarantees, large amounts of public money are invested in this sector. These systems enjoy large public support.

For all these reasons public authorities need legal instruments to guarantee the most effective use of the limited budgets available, to keep prices down, to guide choices between comparable treatments and to guarantee access for all to high quality care.

We will analyse to what extent the Commission proposal could put these necessary regulatory powers of the public authorities under pressure. We will focus on the stipulations of the proposal that are potentially the most problematic in this respect.

Freedom of establishment

The Chapter on the freedom of establishment of the proposed Directive¹, obliges Member States to simplify and remove a large number of authorisations and licensing procedures and to limit the number of documents required for access to a healthcare service activity and to the exercise of healthcare provision.

The authorisation schemes in question do not only concern those that healthcare providers have to comply with, but also those that the patient needs before having access to a service. This means that it is also applicable to prescriptions, referral documents, etc.

According to Article 15, Member States have to set up a major screening exercise to identify and assess procedures and conditions that care providers have to comply with. They must verify that these requirements are non-discriminatory, necessary and proportional. If not, the conditions should be changed or abolished. The conditions that need to be screened contain the basic instruments of the healthcare authorities. We would mention the rules on planning, necessary to guarantee a balanced geographical spread of healthcare supply², the price fixing mechanism³, guaranteeing affordable prices, the legal form of the healthcare provider such as being a non-profit making organisation), staff norms in healthcare institutions⁴ and referral systems⁵. After the entry into force of the proposal for a Directive, Member States can no longer introduce any new requirements of this sort, unless the need for it arises from new circumstances⁶. The Commission will examine the compatibility of any new requirements with Community law, and can request to refrain from adopting or to abolish the requirement⁷.

Assessing whether these legal instruments are not disproportionate or discriminatory may be useful. However, the Commission proposal will create a tremendous legal uncertainty for healthcare authorities. It is not specified how the criteria for non-discrimination and proportionality, but most importantly necessity, will be applied to the healthcare sector. Which regulations will be accepted as “justified by an overriding reason relating to the public interest”?

Furthermore, the stipulation that the only ground for new regulations after the entry into force of the Commission proposal is “new circumstances” risks eroding the national steering capacity to organise healthcare systems. It would also lead to further legal uncertainty. How would the European Commission interpret what is “a new circumstance” in the healthcare sector? Is the risk of exceeding the available budget a new circumstance and by how much must the budget be exceeded to be considered as a new circumstance? Is increasing specialisation in healthcare provision a new circumstance? What about increased awareness that healthcare is becoming less accessible to some or, on the contrary, too widely used by others?

¹ Chapter II.

² Article 15, 2 (a).

³ Article 15, 2 (g).

⁴ Article 15, 2 (f).

⁵ Article 15, 2 (i).

⁶ Article 15, 5.

⁷ Article 15, 6.

The European Commission can oblige national healthcare authorities to abolish or change regulations. However, the Commission can only verify whether the health care regulations are in conformity with the Commission proposal for a Directive and the internal market rules, but not whether they are necessary and effective to achieve their basic objectives, that is to guarantee to their citizens high-quality services accessible for all. Thus the Commission cannot take over the responsibilities and obligations of the Member States, but they decide and the national level loses thus the capacity to steer the system.

Principle of the country of origin

Based on the principle of the Country of origin⁸ healthcare providers that want to provide care on a temporary basis in another Member State than the Member State where they are established, would be allowed to do so without being subject to the national provisions of the Member State where they provide this care, but only of the Member State of establishment. This counts e.g. for provisions related to access to and exercise of the care provision, in particular those requirements governing the behaviour of the care provider, the quality or content of the care, advertising, contracts and the provider's liability. Member States may not impose on healthcare providers established in another Member State an obligation, e.g. to make a declaration or notification to the competent authorities; to apply specific contractual arrangements between the provider and the recipient or to possess an identity document issued by its competent authorities specific to the exercise of the service activity. They may not forbid the provider to set up a certain infrastructure such as an office with consulting rooms.

The extent to which the exercise of regulated healthcare professions (e.g. doctors, nurses, pharmacists, midwives) would be exempted from this principle⁹ is not clear in the Commission proposal and depends also on the outcome of the negotiations concerning the review of the legislation on the recognition of professional qualifications. Even if all the stipulations of the proposal for a Directive on professional qualifications would be exempted from the Country of origin principle, this would not necessarily guarantee that health professionals should provide services with the same rights and obligations as the nationals of the host Member State. The political agreement in the Council on the proposal for a Directive on the recognition of professional qualifications requires that the disciplinary rules of the host Member State are applicable. However, it does not specify which legislation is applicable for the other professional rules such as the organisation of the profession, control and professional liability. It is thus not at all clear whether and to what extent the host Member State would be able to force a healthcare professional established abroad, providing care on its territory, to comply with rules of conduct applicable to national providers such as on the continuity of care, conditions for prescribing a treatment or product, the scope of activity of a professional group (e.g. the definition of which professional is allowed to exercise which medical act) or the regulations on advertising.

It is highly questionable whether, and not at all clear how other general derogations from the country of origin principle¹⁰ might be applicable to healthcare services. The case by case derogations on the other hand¹¹ are only applicable to a given provider in an individual case, in exceptional circumstances and after a lengthy procedure.

⁸ Article 16.

⁹ Art. 17(8).

¹⁰ Article 17.

¹¹ Article 19.

Many crucial questions remain unanswered. If a healthcare provider provides care on a temporary basis in another Member State, does the social protection system of the host Member State have to fund this care? If so, at what tariff and under what conditions? This leads again to the fundamental question of what is the value of the (contractual) relationship between the provider and the (public) financiers? Which requirements are the financiers allowed to impose and how does this relate to the country of origin principle? In other words, would Article 23 also apply to a provider that moves to the patient instead of the patient that moves to the provider and how would this apply? If on the other hand, the social protection system of the host Member State must not fund this care, how can the patient know whether the provider he consults is integrated in the funding system or not?

If a healthcare provider provides temporarily for instance pharmaceutical products or laboratory tests (e.g. on wheels), which prices do they have to apply, which regulation related to advertising, prescriptions, quality and information to the patients apply? Can they provide pharmaceutical products that are prescription-only drugs in the host Member State without prescription when they can be sold without prescription in the home Member State? Can these providers bypass national planning regulations in the host country?

The temporary nature of the activity is not clearly defined. If a healthcare provider established in a Member State provides e.g. 16 weeks a year of care in each of 3 host Member States, should he do so under the principle of the country of origin or should he establish himself in the “host” country?

What about situations in which patients have no choice? For instance, is an emergency ambulance service connected with a private for-profit hospital allowed to pick up victims of road or skiing accidents on the other side of the border and bring them to the hospital he is connected with? Who has to pay the bill for the care of these patients and at which rate? Which legislation would apply to phone consultations and to healthcare provided from a distance e.g. through e-health?

How can a healthcare provider ensure continuity of care if he temporarily provides care to patients of another Member State? The Commission proposal for a Directive only stipulates that the care provider should supply a postal address, fax number or e-mail address to which patients can send a complaint or request for information on the care provided¹², and that the care provider should supply the recipient, at his request, with information on the existence or otherwise of an “after-sales guarantee” including the period of validity of the after sales guarantee¹³ ...

If this proposal were to become law, healthcare providers established in a Member State that imposes lower conditions on the provision of healthcare could, based on the legislation of this Member State, provide care in other Member States, and compete with the healthcare providers of host Member States that do have to comply with more legal requirements. This would lead to reversed discrimination and would consequently put pressure on regulations in host Member States and provoke a spiral of deregulation. Healthcare systems that opt for more private and for-profit care provision in their country, could easily export these private elements to other countries.

¹² Article 32.

¹³ Article 28.

According to the proposal for a Directive, the Member State of origin is also responsible for supervising the provider and the care provided abroad. Apart from the question as to the feasibility of supervision by the Member State of origin, we can question the legitimisation and motivation of a public authority to control healthcare services provided abroad to citizens of another Member State. The authorities of the Member State of origin do not have to give account of their conduct to the citizens of the host Member State, receiving the care.

Member States must also ensure that patients can obtain in their Member State of residence information including information on the legislation applicable in other Member States related to the access to and exercise of the (healthcare) service activity, in particular those relating to consumer protection¹⁴. Member States should also ensure that providers make certain information available to patients¹⁵, e.g. his professional title and the Member State in which it has been awarded; the contractual clauses determining the law applicable to the contract; the price of the service; a reference to the professional rules applicable in the Member State of origin. Nowhere is it stated in which language all this information should or may be provided.

However, healthcare systems are extremely complex and it is problematic to make citizens understand the healthcare system of their own country. How could one expect a citizen to understand the systems of 25 countries, all potentially operational on the territory of his country and to expect him to make an informed choice between providers? Moreover, patients are not ordinary consumers, as they need this information at a time when they are in a vulnerable and dependent position, because they need care. The timely reception of adequate care can be vital. Furthermore it is not clear in the proposal who is responsible if the information is not correct or not provided in time.

Assumption of the costs for healthcare provided in another Member State

In Article 23 the Commission's proposal for a Directive defines the conditions under which national social security systems must reimburse the costs of medical care received in other Member States. These proposed provisions are based on the European Court of Justice's case law. However, where Member States complained about the lack of legal certainty, due to the Court rulings, the Commission proposal for a Directive does not add clarity.

According to Art 23, the assumption of the cost of non-hospital care provided in another Member State may not be subject to the granting of an authorisation where the cost of this care, if it had been provided on their territory, would have been assumed by their social security system. Patients must be reimbursed by their Member State of affiliation to the extent and at the tariff that the services concerned would normally be reimbursed if administered in the home Member State. The conditions and formalities to which the provision of non-hospital care on their territory is subject, may be imposed for reimbursement of care received abroad. It is however not at all clear which conditions and formalities can be imposed on care provided abroad. Can healthcare funding institutions require that the healthcare providers established abroad comply with conditions related to the cost-effective use of public money, such as guidelines or standards for medical care? Can healthcare purchasers require that healthcare providers abroad enter into a contractual relationship with them before they fund their care? Do care providers established abroad have to respect the tariffs fixed for home country providers? Can the healthcare financier reclaim money if the group of providers he belongs to has exceeded a previously fixed budget ceiling, if this is applicable to providers in its own country? Etc...

¹⁴ Article 22.

¹⁵ Article 26.

The assumption of the costs of healthcare provided in another Member State may not be less than that provided for by their own social security system in respect of similar healthcare provided on their territory. This provision is based on the Court of Justice Judgement Vanbraekel. However, where this judgement concerned programmed hospital care abroad, the Commission proposal for a Directive extends the principles of this Judgement to the reimbursement of all healthcare received abroad. This would mean that the procedure for funding healthcare abroad, based on Regulation 1408/71 (tariff and reimbursement rate of the country of the care provision) would in the future only be applicable when the reimbursement level in the Member State where the care is given is more advantageous for the patient. It also remains unclear whether financing institutions can apply different reimbursement rates for contracted and non contracted care (abroad or in the own country).

For hospital care in another Member State, the proposed Directive stipulates that Member States are still allowed to require prior authorisation. The authorisation must be granted if the care concerned would normally be reimbursed in the home Member State but cannot be delivered there within a time limit which is medically justifiable, taking into account the patient's current state of health and the probable course of the illness. Hospital care is defined as medical care which can only be provided within a medical infrastructure and which normally requires the accommodation of the person receiving the care within this structure. This definition remains vague, however, and can for example easily be interpreted differently in the country of affiliation and in the country where the care is provided. The simple example of childbirth is illustrative in this context. In some Member States deliveries are almost exclusively done in a hospital, by a gynaecologist. In others, women deliver at home with a midwife or their GP.

Other aspects

The proposed Directive moreover lifts bans on advertising for regulated (healthcare) professions, while stipulating that such advertising has to respect rules in particular in relation to the independence, dignity and integrity of the profession, as well as professional secrecy¹⁶. However, advertising aims to increase consumption, not necessarily of the best quality care for the best price.

Conclusion

The proposal for a Directive on services in the internal market does not take into account the specificity of the healthcare sector, where extensive regulation is needed to redress market imperfections and to guarantee the accessibility of high quality care to all citizens. The proposal does not take into account the involvement of a third party in the healthcare sector, the (public) financier of the care service. This financier needs to be able to enter into a contractual relationship with care providers and impose cost-effective behaviour on providers, in order to be able to guarantee the financial viability of the systems.

The proposal leaves many crucial questions unanswered related to their application in the healthcare sector. The Commission's proposal would lead to an important legal uncertainty for public authorities, providers and patients and to a multiplication of cases before the Court of Justice.

¹⁶ Article 29.

The proposal would inevitably lead to deregulation in this sector where regulation is a crucial element for quality- and cost control. Deregulation would lead to more exploitative behaviour by care providers and thus to higher prices, provision of more unnecessary care and of needless highly specialised care. In short, (public) healthcare financiers would lose control over their expenditure and this would harm the financial viability of national healthcare systems, and the EU macro economic policy objectives.¹⁷

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¹⁷ Two examples to illustrate this:

In the US, where in the last decade there has been a transformation of both funding and provision of healthcare onto a fully market-based, for-profit basis, health care expenditures are high and increasing, coverage and access is falling, administrative and other transaction costs are skyrocketing, quality of care has been eroded, and regulation is weak and inadequate (Saltman, R. B., "Constructing Health Security in Europe: Looking Backward to See Forward", Paper prepared for delivery at the conference on European Integration and Health Care Systems: A Challenge for Social Policy, Ghent, 7-8 December 2001)

An EU example of how the free movement provision would inevitably lead to deregulation and higher prices in the healthcare sector can be found in Luxembourg. After the ECJ Kohll and Decker judgments the Luxembourg medical corps felt that the opening of the borders and the reimbursement of care provided by non-contracted foreign providers constituted discrimination. Consequently, all discussions concerning the establishment of profiles of medical activity with a view to tracing abuses have been blocked since then. Furthermore, Luxembourg physicians demanded to withdraw from the compulsory convention system that compels doctors to comply with the imposed tariffs. In response, the government has been obliged to increase fees by 6.5% on average. (Kieffer, R., "L'impact de la jurisprudence européenne sur la politique sanitaire et sociale au Luxembourg", Présentation in Lille (France), 5 December 2003)