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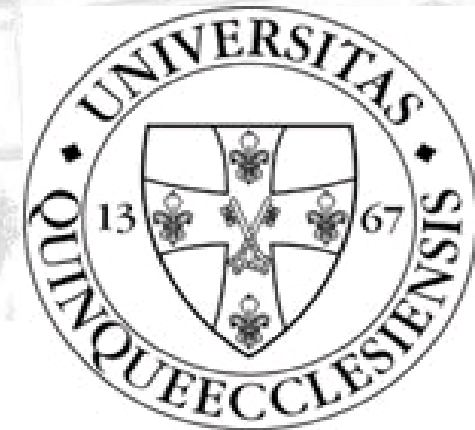


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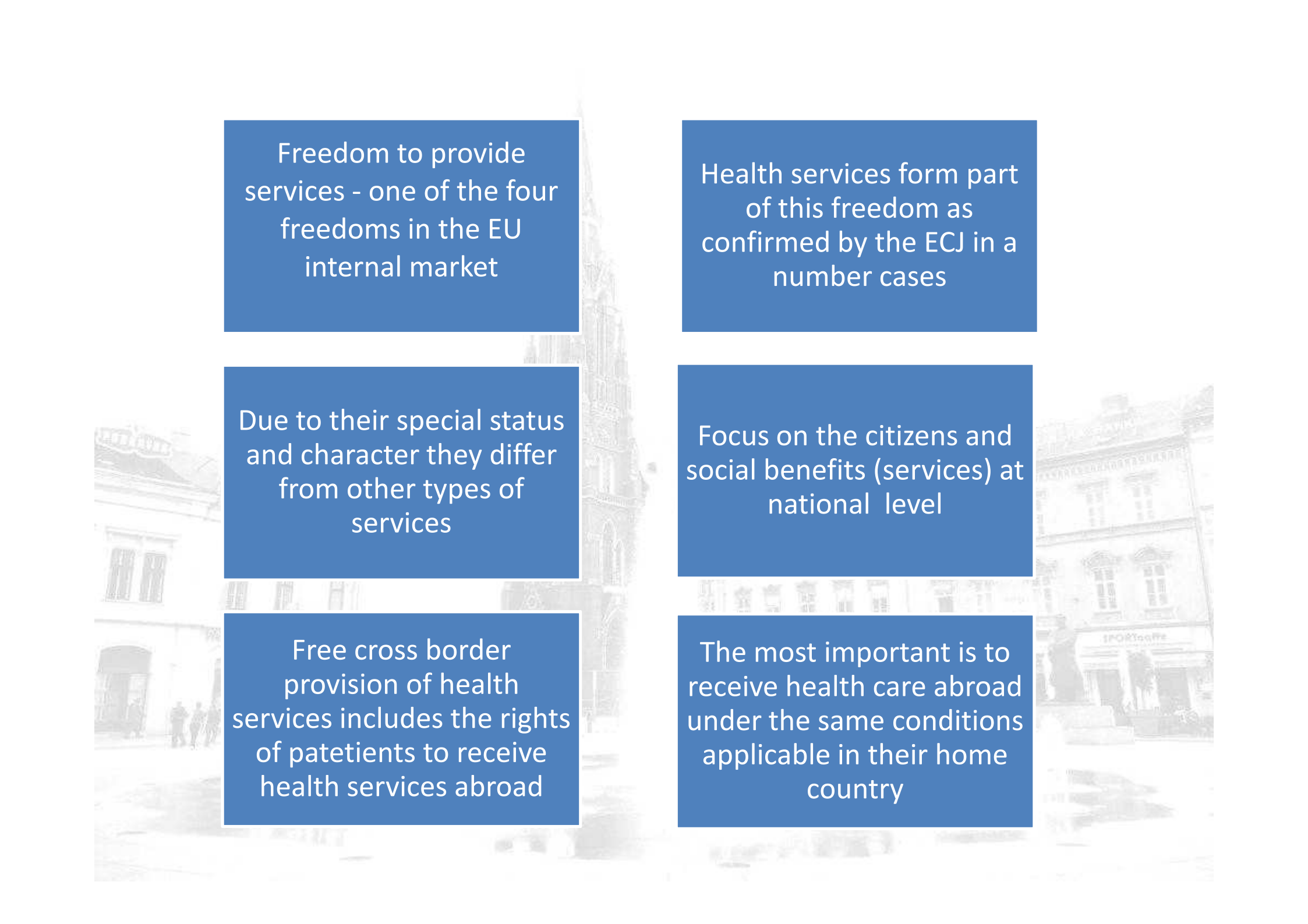
The specificities of providing cross-border healthcare services in the EU

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CONTEMPORARY LEGAL CHALLENGES:

EU – HUNGARY – CROATIA

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Freedom to provide services - one of the four freedoms in the EU internal market

Health services form part of this freedom as confirmed by the ECJ in a number cases

Due to their special status and character they differ from other types of services

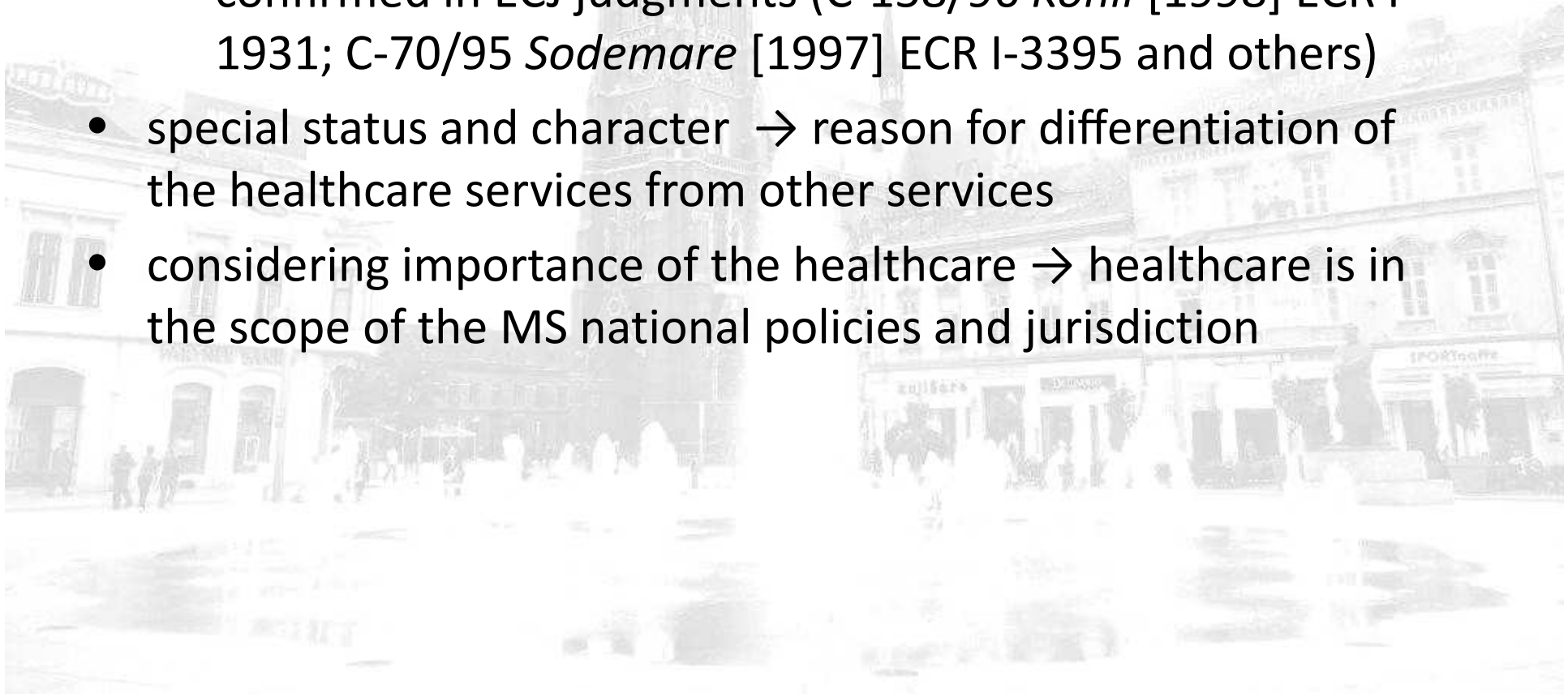
Focus on the citizens and social benefits (services) at national level

Free cross border provision of health services includes the rights of patients to receive health services abroad

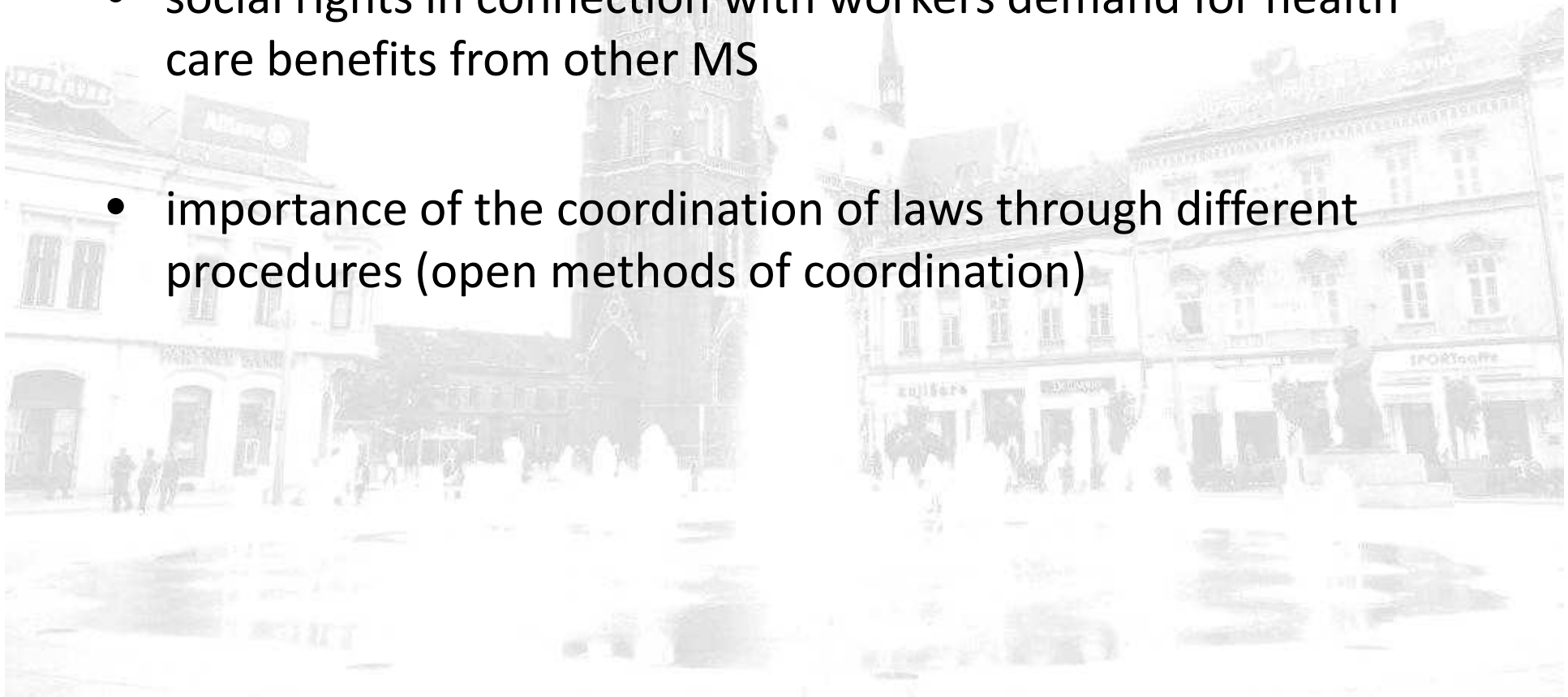
The most important is to receive health care abroad under the same conditions applicable in their home country

Freedom to provide healthcare services

- part of the freedom to provide services
 - guaranteed by the provisions of the Art. 56 and 57 TFEU
 - confirmed in ECJ judgments (C-158/96 *Kohll* [1998] ECR I-1931; C-70/95 *Sodemare* [1997] ECR I-3395 and others)
- special status and character → reason for differentiation of the healthcare services from other services
- considering importance of the healthcare → healthcare is in the scope of the MS national policies and jurisdiction



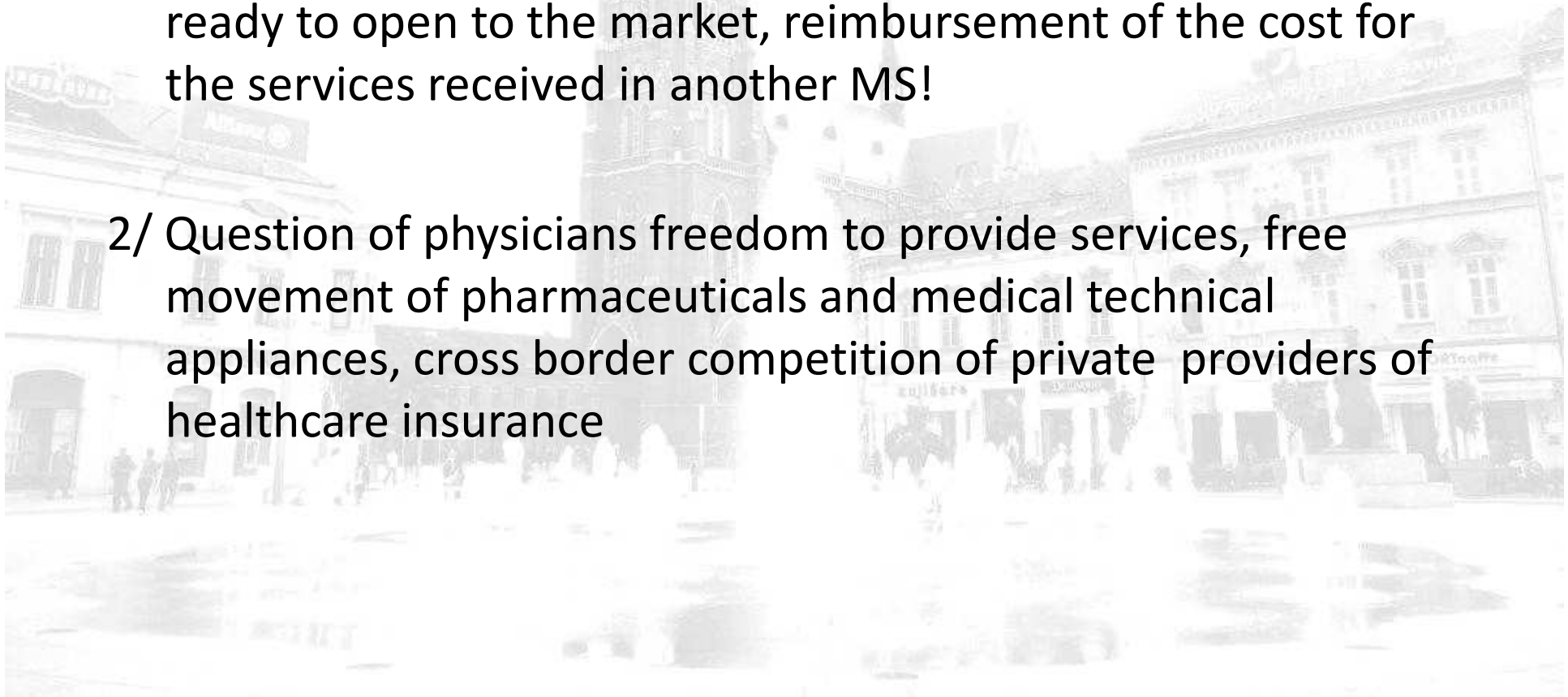
- influence of the freedom to provide services in the area of healthcare also affects other freedoms and different specific areas such as freedom of movement of workers and members of their families
- social rights in connection with workers demand for health care benefits from other MS
- importance of the coordination of laws through different procedures (open methods of coordination)



Internationalisation, globalization, free flow of capital, workers mobility and entrepreneurship have raised new issues regarding healthcare services

1/ Question of boundaries to which health care insurers are ready to open to the market, reimbursement of the cost for the services received in another MS!

2/ Question of physicians freedom to provide services, free movement of pharmaceuticals and medical technical appliances, cross border competition of private providers of healthcare insurance



THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION

Art. 168 (1) TFEU:

- A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities

Art. 168 (7) TFEU:

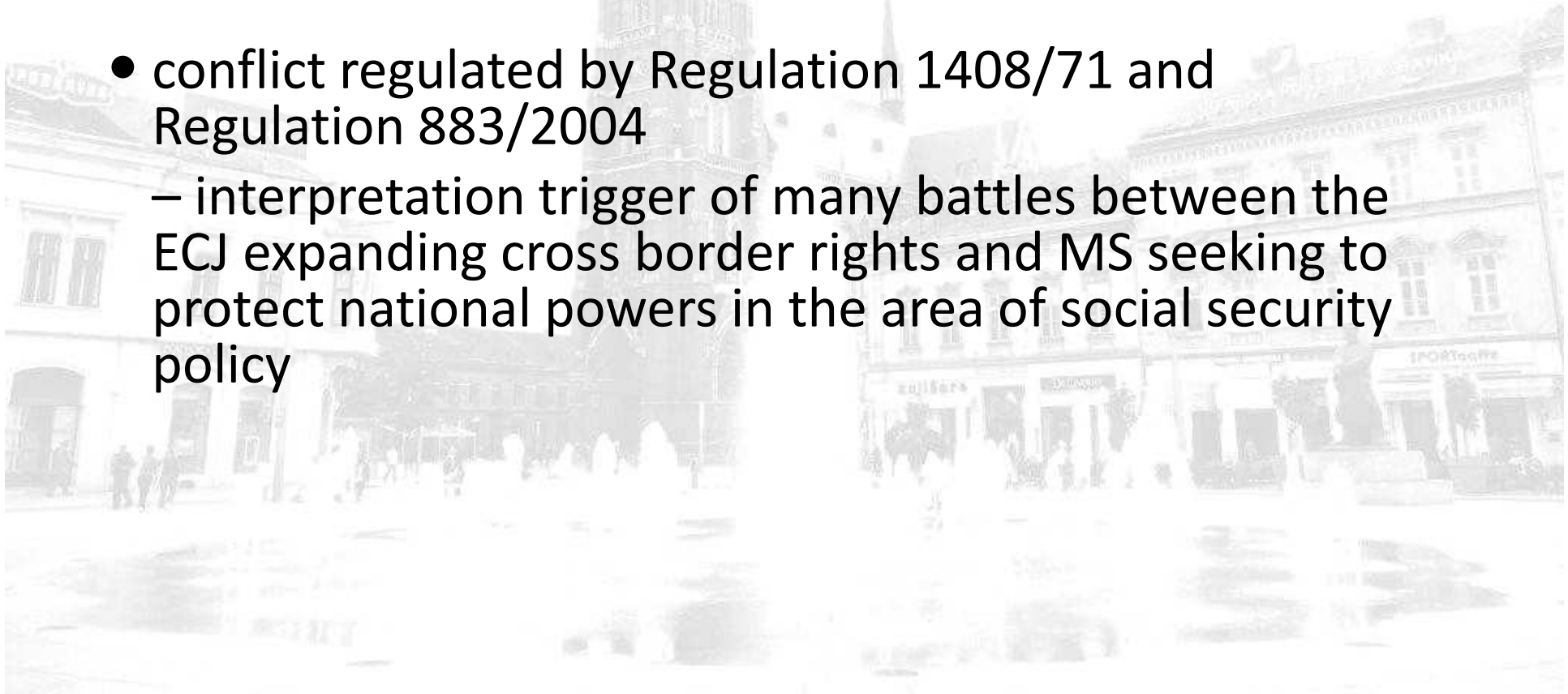
- Union action shall respect the responsibilities of the MS for the definition of their health policy and for the organization and delivery of health services and medical care (confirmed in judgment C-372/04 Watts, para 146 and other)
→ that provision does not, however, exclude the possibility that the MS may be required (under other Treaty provisions, such as Article 56 TFEU, or EU measures adopted on the basis of other Treaty provisions) to make adjustments to their national systems of social security.

Principle of individual cross-border choice inherent in European free movement rights

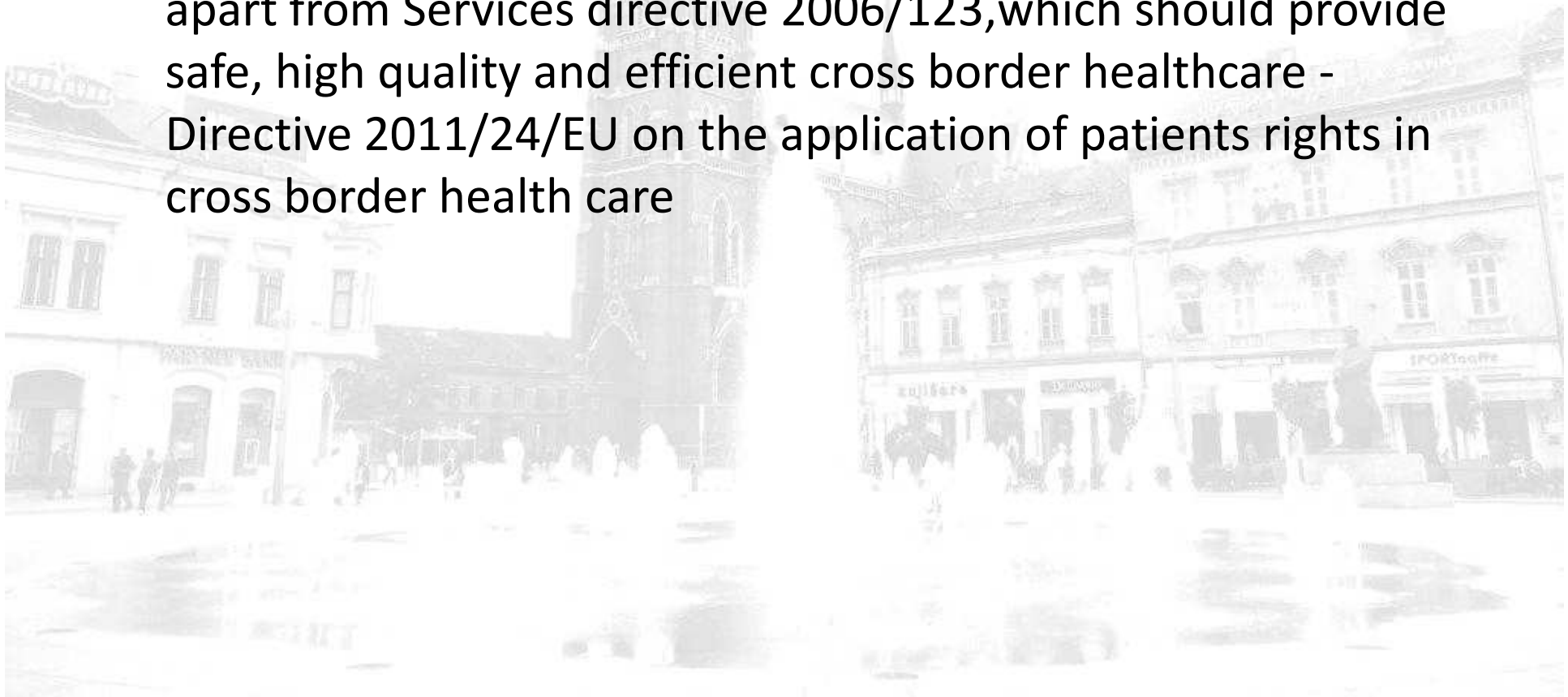
vs.

Principle of solidarity that defines national healthcare systems in EU countries

- conflict regulated by Regulation 1408/71 and Regulation 883/2004
 - interpretation trigger of many battles between the ECJ expanding cross border rights and MS seeking to protect national powers in the area of social security policy

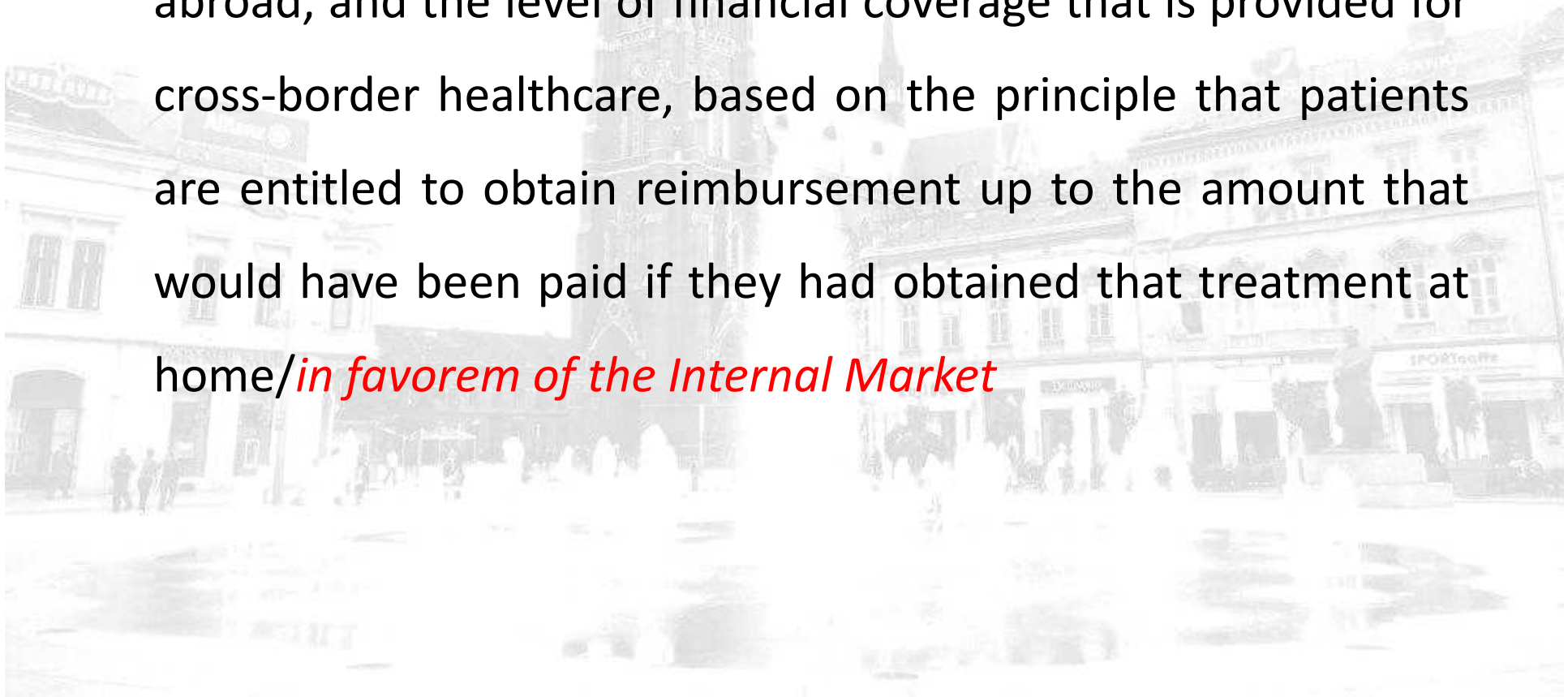


- rules for receiving cross-border healthcare services and reimbursement of the costs - not always clear or easy: development achieved through ECJ case law
- regulatory framework:
apart from Services directive 2006/123, which should provide safe, high quality and efficient cross border healthcare -
Directive 2011/24/EU on the application of patients rights in cross border health care



specific framework for cross-border healthcare:

- the entitlements of patients to have healthcare in another MS, including the limits that MS can place on such healthcare abroad, and the level of financial coverage that is provided for cross-border healthcare, based on the principle that patients are entitled to obtain reimbursement up to the amount that would have been paid if they had obtained that treatment at home/*in favorem of the Internal Market*



THE ECJ CASE LAW:

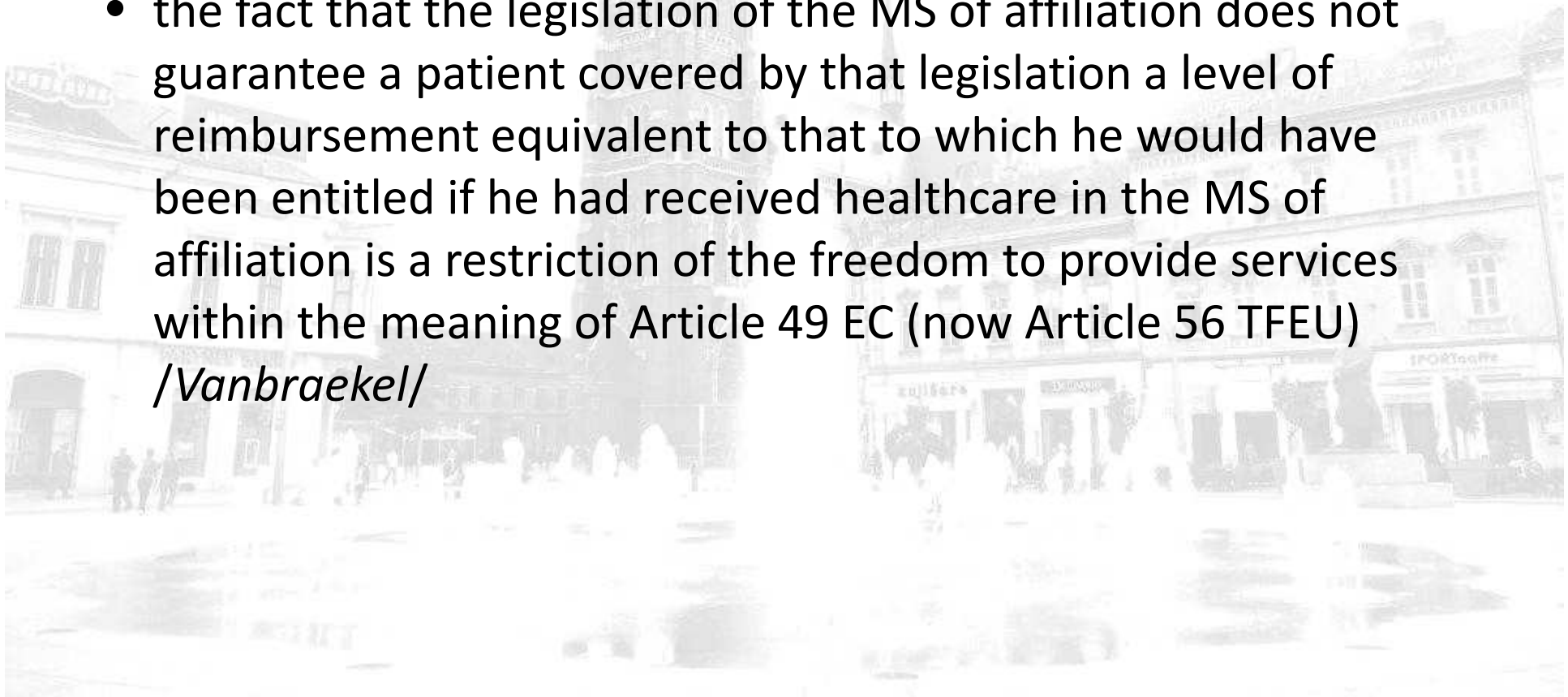
The right to reimbursement of the costs of healthcare provided in another MS from the statutory social security scheme of patients as insured persons was recognized by the ECJ in several judgments:

- Case C-158/96 *Kohll* [1998] ECR I-1931
- Case C-120/95 *Decker* [1998] ECR I-1831
- Case C-368/98 *Vanbraekel* [2001] ECR I-5363
- Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473
- Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4503
- Case C-372/04 *Watts* [2006] ECR I-4325
- Case C-173/09 *Elchinov* [2010] ECR I-0000 - confirmed all the previous case law



The ECJ ruling:

- the freedom to provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another MS in order to receive those services there */Kohll/*
- the fact that the legislation of the MS of affiliation does not guarantee a patient covered by that legislation a level of reimbursement equivalent to that to which he would have been entitled if he had received healthcare in the MS of affiliation is a restriction of the freedom to provide services within the meaning of Article 49 EC (now Article 56 TFEU) */Vanbraekel/*

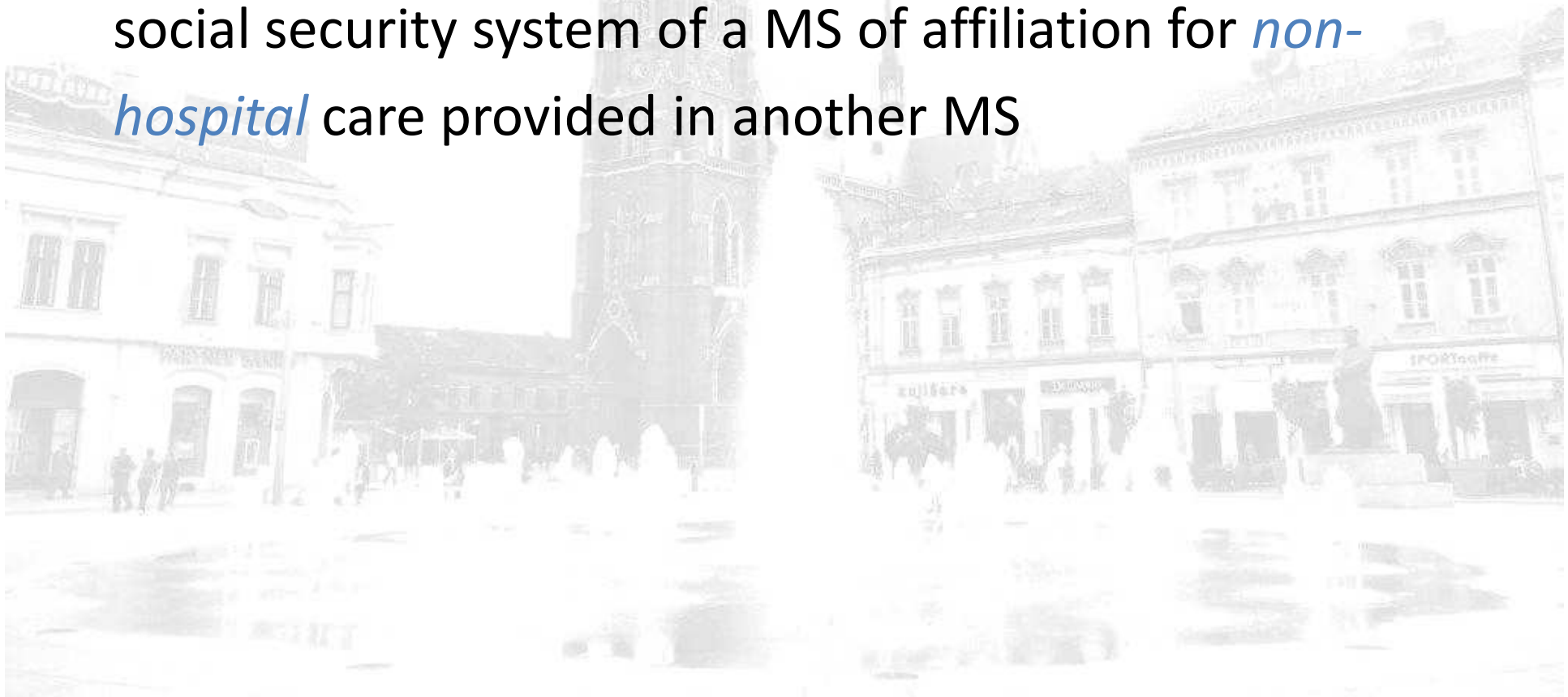


ECJ has established the basic principle:

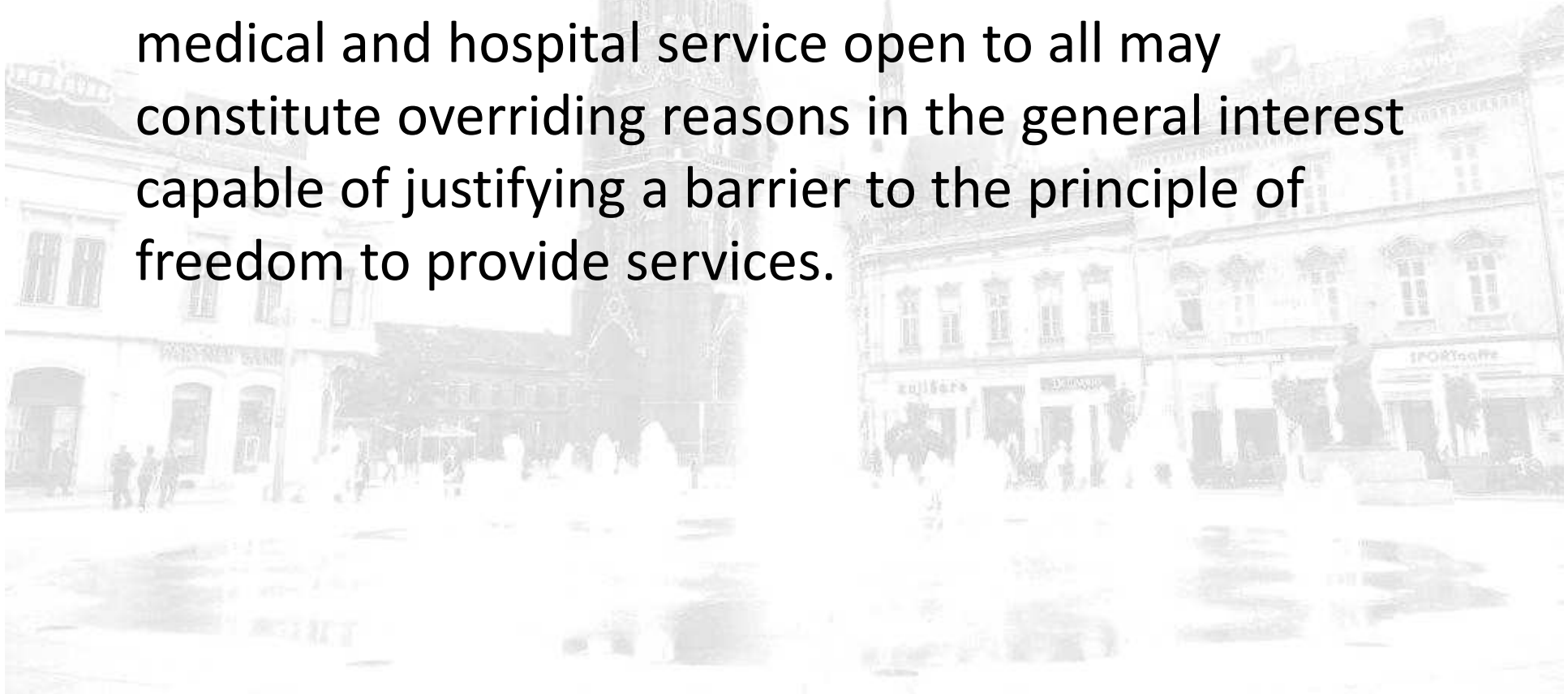
- healthcare services are within the scope of the Article 56 TFEU (freedom to provide services) and
- Article 56 TFEU cover freedom to provide services and freedom to receive services



- in the light of the case-law of the ECJ it is not appropriate to establish or maintain the requirement of any prior authorization for reimbursement by the social security system of a MS of affiliation for *non-hospital* care provided in another MS

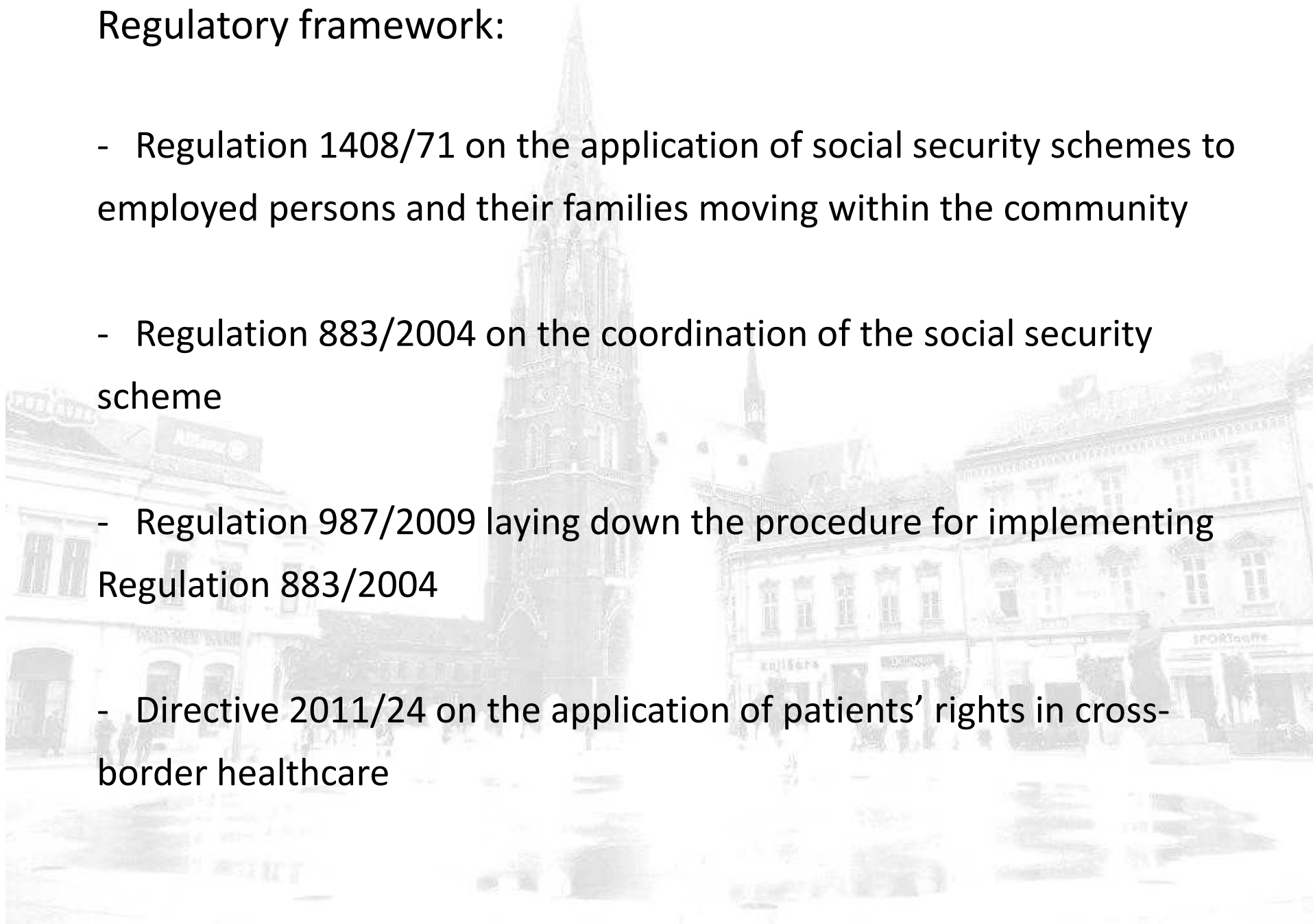


- as regards *hospital care*, the ECJ has recognized that it cannot be excluded that the possible risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services.



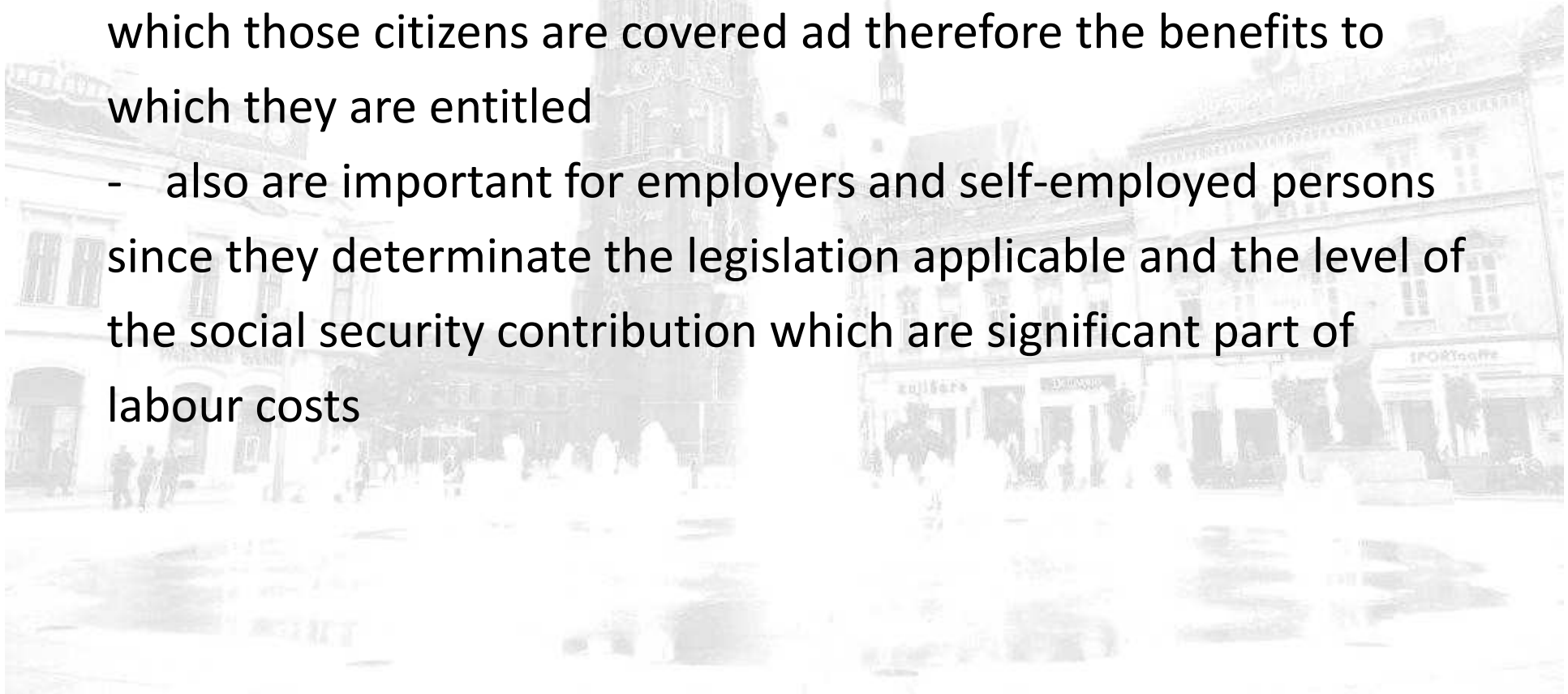
Regulatory framework:

- Regulation 1408/71 on the application of social security schemes to employed persons and their families moving within the community
- Regulation 883/2004 on the coordination of the social security scheme
- Regulation 987/2009 laying down the procedure for implementing Regulation 883/2004
- Directive 2011/24 on the application of patients' rights in cross-border healthcare



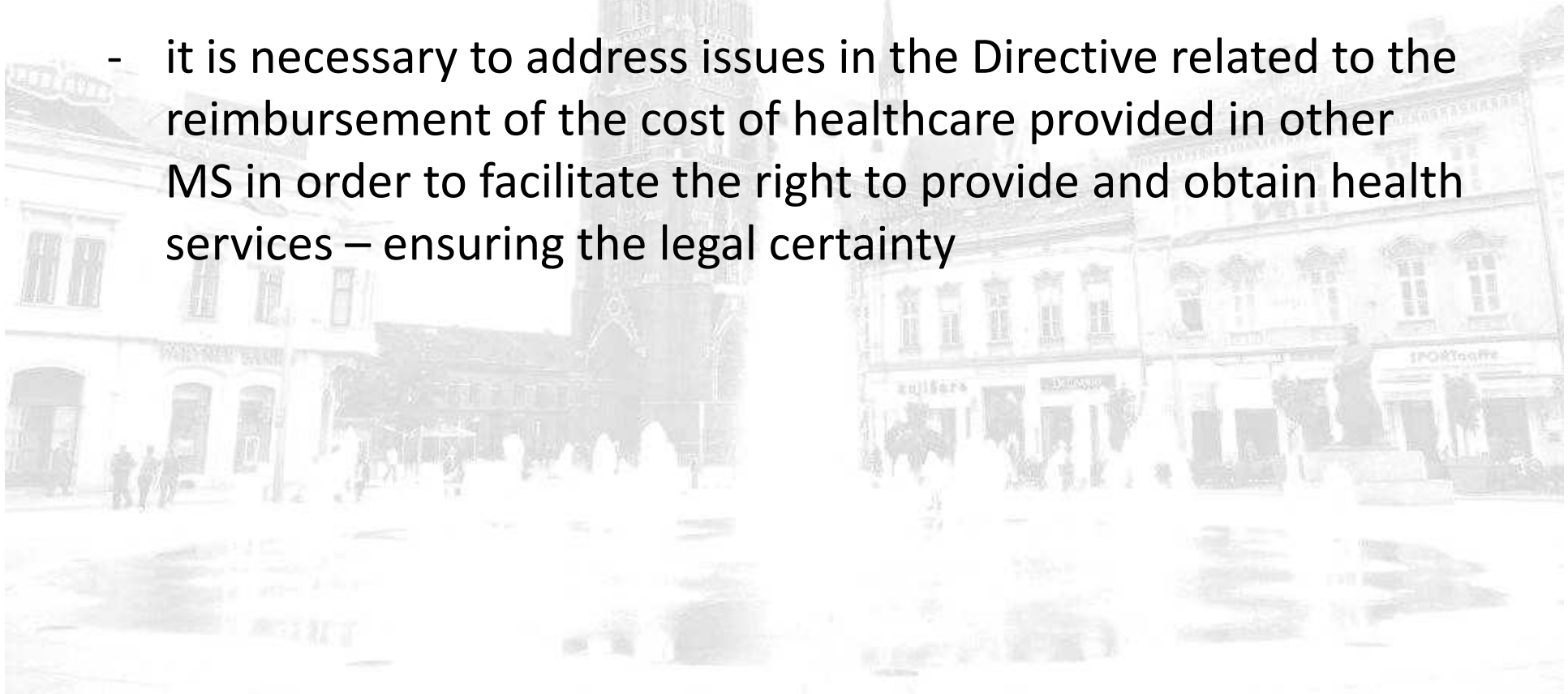
Rules on conflict of law constitute

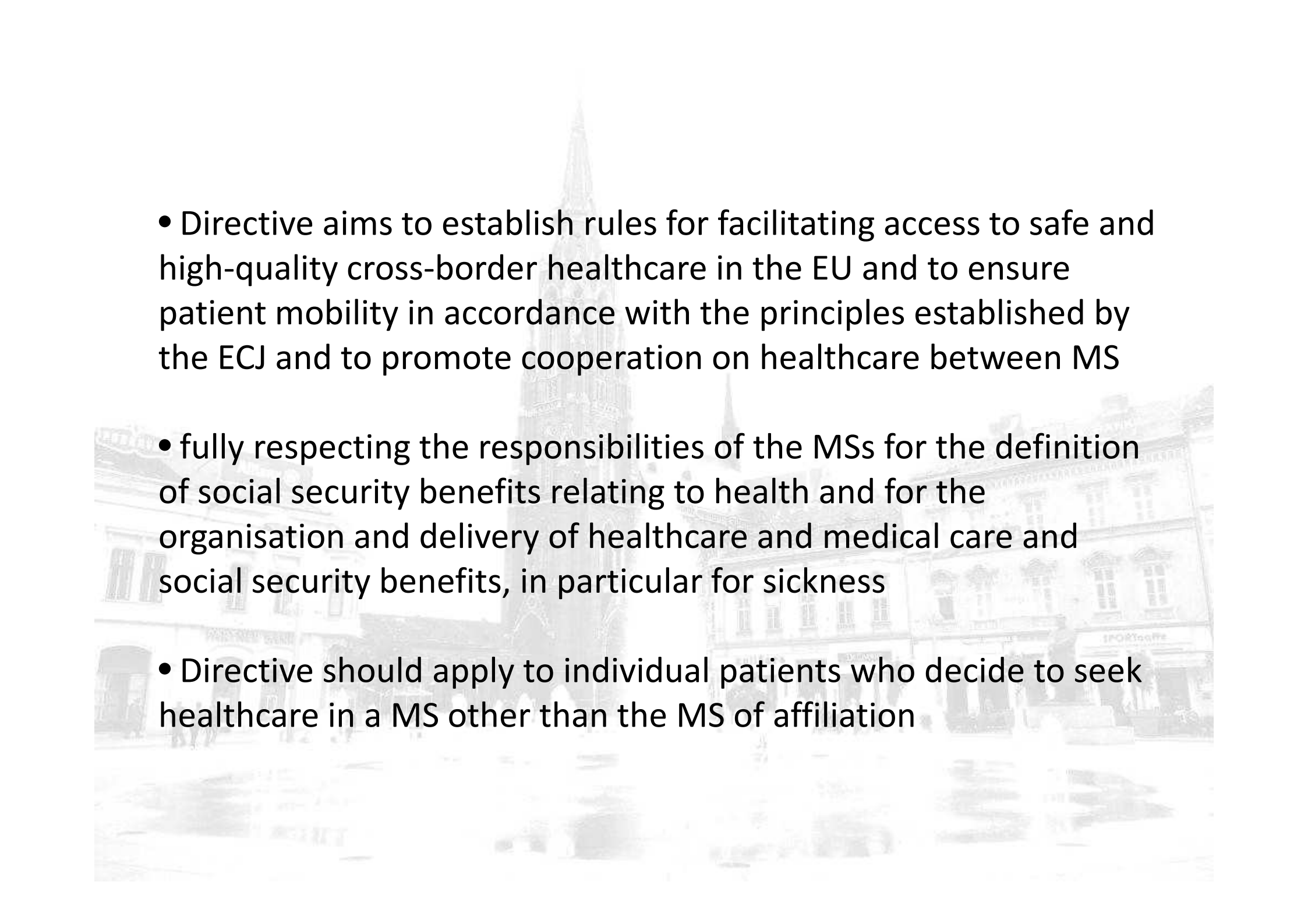
- the core of coordinating EU regulations 883/2004 and 987/2009
- important for the EU citizens and other persons subject to coordination since they regulate social security legislation by which those citizens are covered and therefore the benefits to which they are entitled
- also important for employers and self-employed persons since they determine the legislation applicable and the level of the social security contribution which are significant part of labour costs



DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare

- it is necessary to address issues in the Directive related to the reimbursement of the cost of healthcare provided in other MS in order to facilitate the right to provide and obtain health services – ensuring the legal certainty



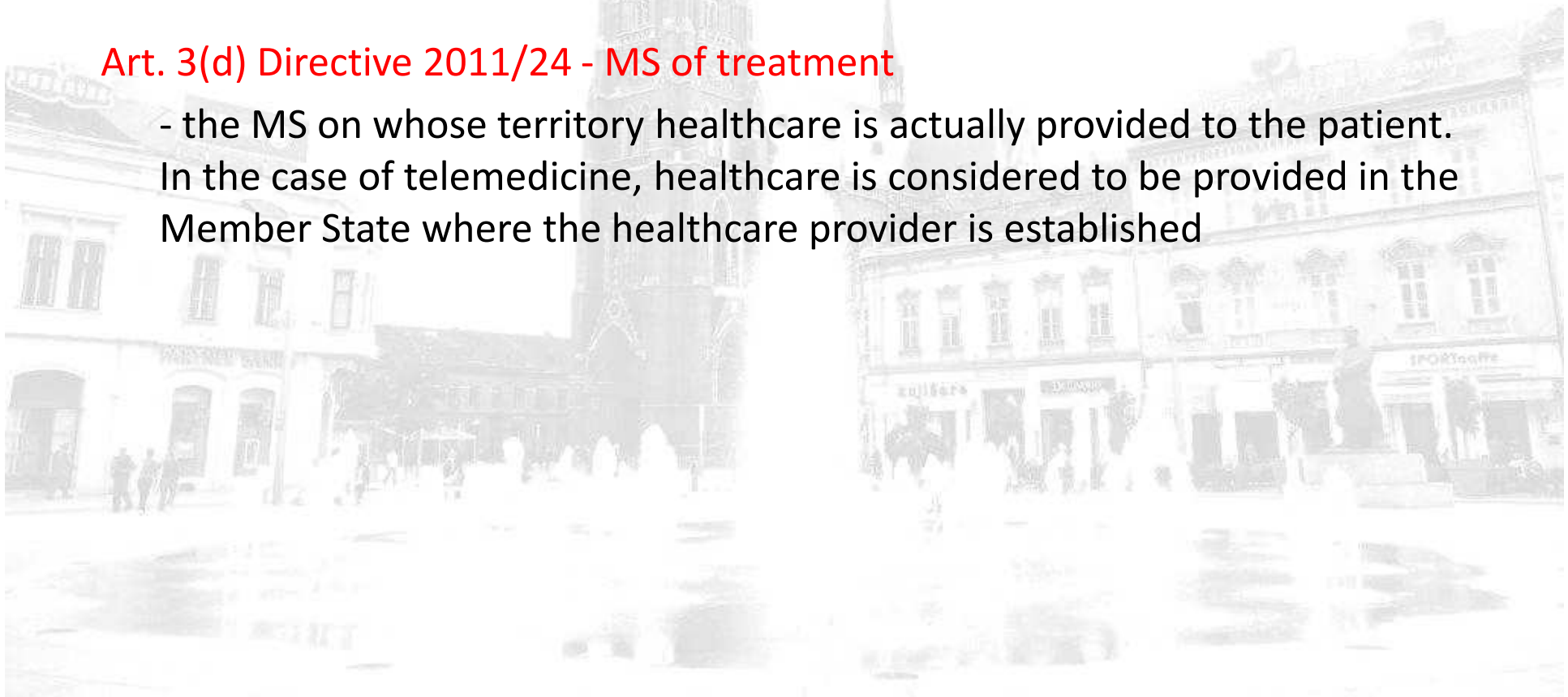
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- Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the EU and to ensure patient mobility in accordance with the principles established by the ECJ and to promote cooperation on healthcare between MS
 - fully respecting the responsibilities of the MSs for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness
 - Directive should apply to individual patients who decide to seek healthcare in a MS other than the MS of affiliation

Art.3 (c) Directive 2011/24 - MS of affiliation:

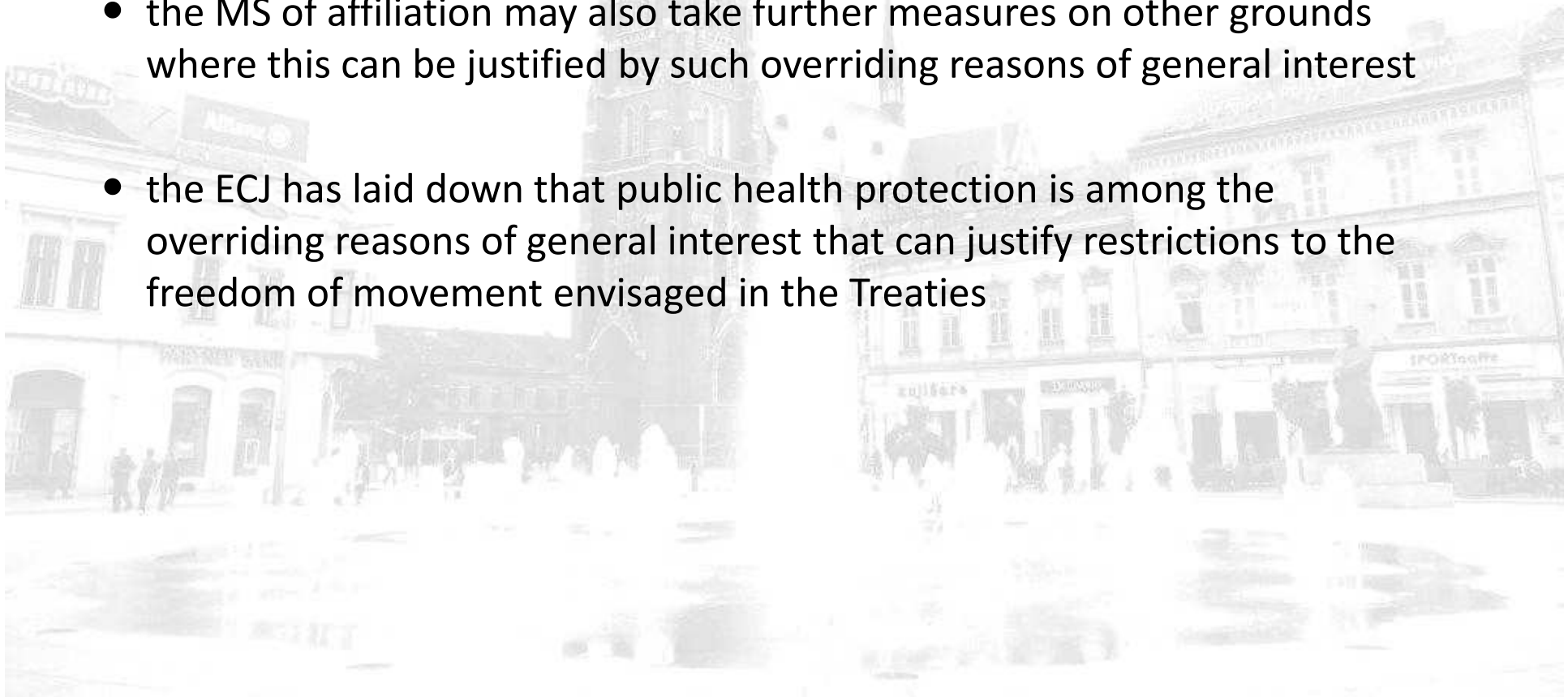
- for insured persons including members of their families, the MS that is competent to grant to the insured person a prior authorization to receive appropriate treatment outside the MS of residence according to Regulations 883/2004 and 987/2009

Art. 3(d) Directive 2011/24 - MS of treatment

- the MS on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established

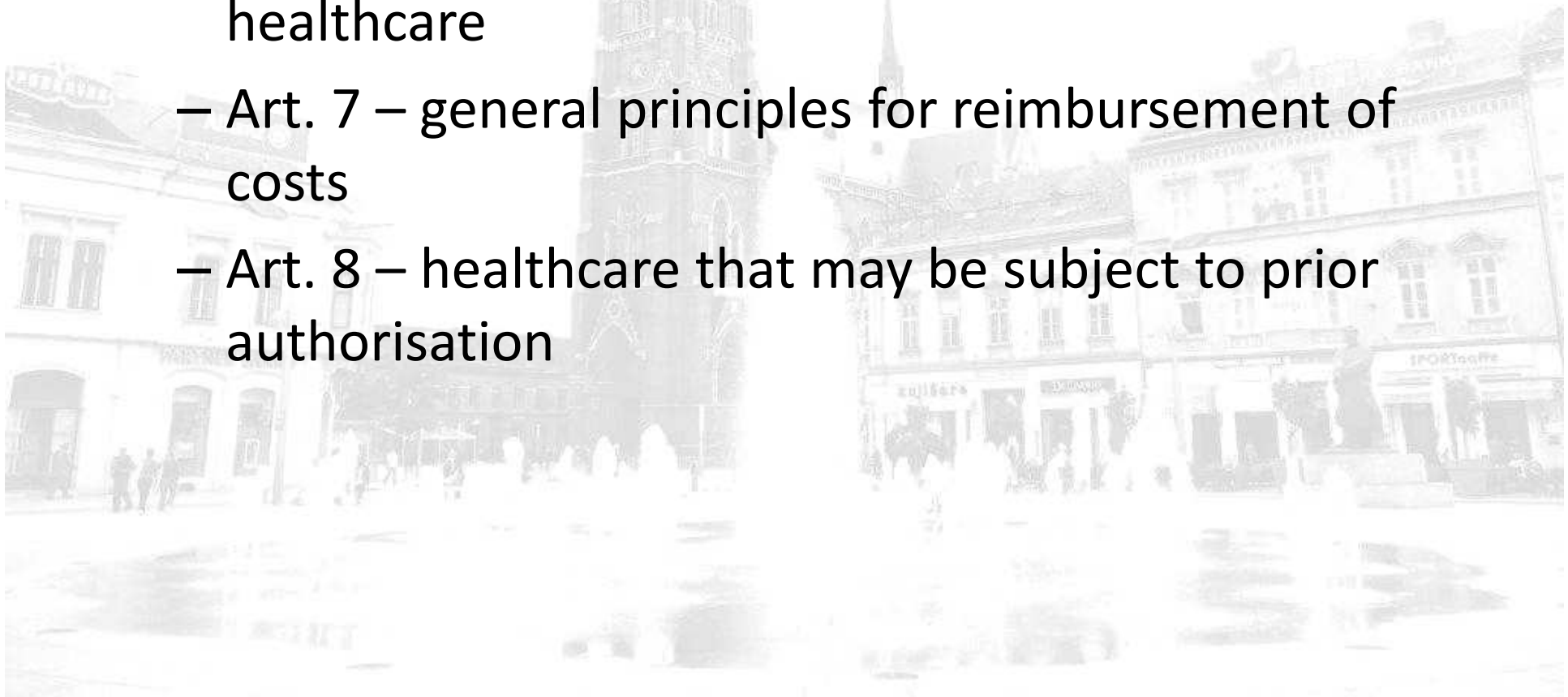


- the MS of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health
- the MS of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest
- the ECJ has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties



- Focus on the most important provisions of the Directive:

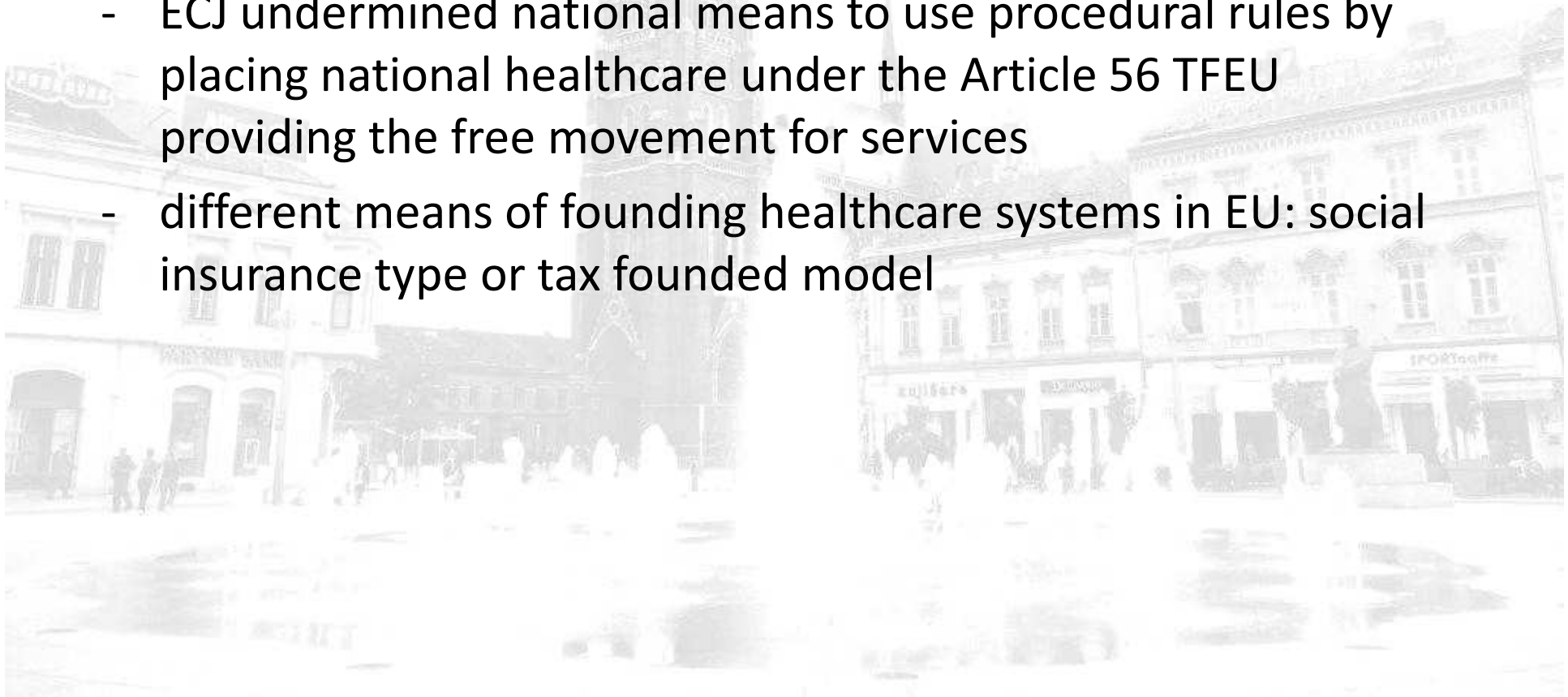
- Art. 5 – responsibilities of the MS of affiliation
- Art. 6 – national contact points for cross-border healthcare
- Art. 7 – general principles for reimbursement of costs
- Art. 8 – healthcare that may be subject to prior authorisation



The transposition of Directive into national legislation and its application should not result in patients being encouraged to receive treatment outside their MS of affiliation!

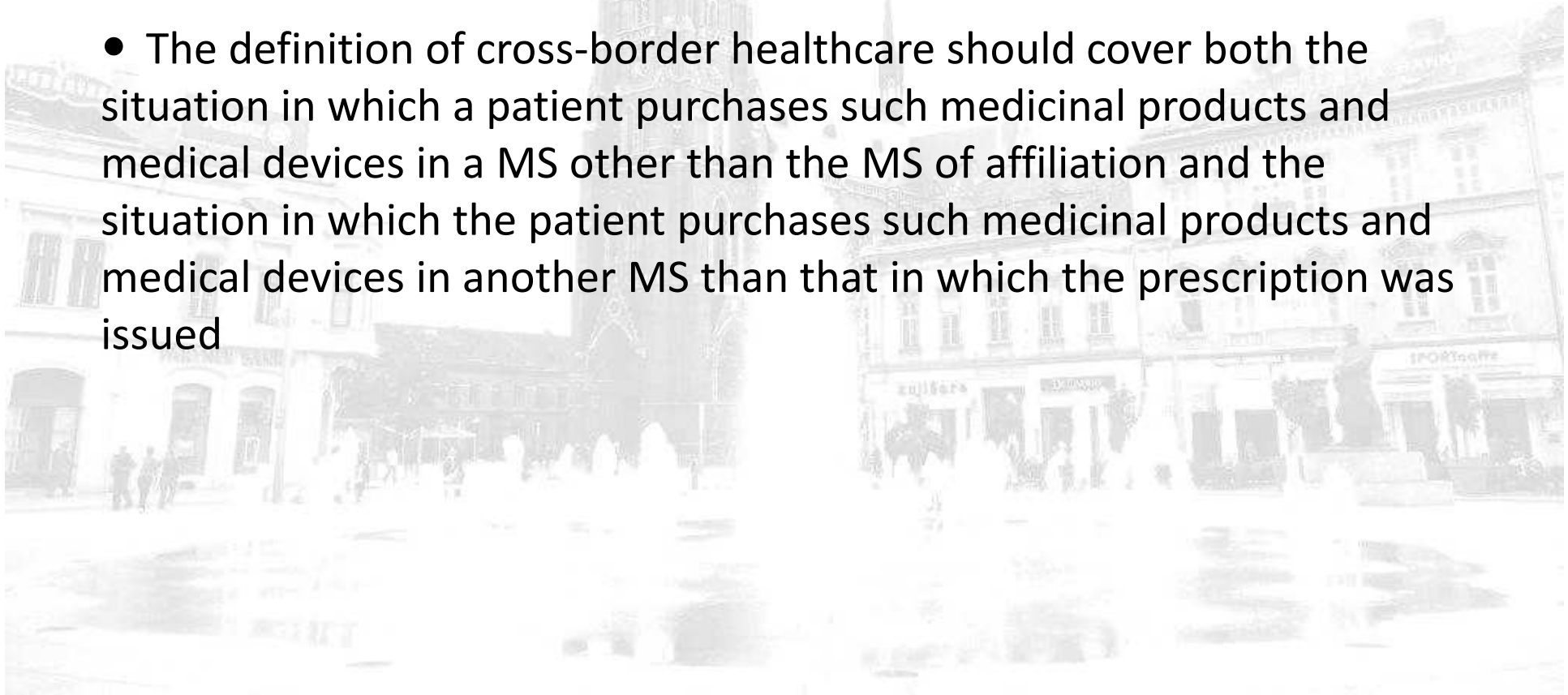


- Procedural restrictions :
 - Healthcare as the responsibility of MS – challenge to prior authorization rules (opportunity of entry and exit to their healthcare system open to providers and patients)
 - ECJ undermined national means to use procedural rules by placing national healthcare under the Article 56 TFEU providing the free movement for services
 - different means of founding healthcare systems in EU: social insurance type or tax founded model

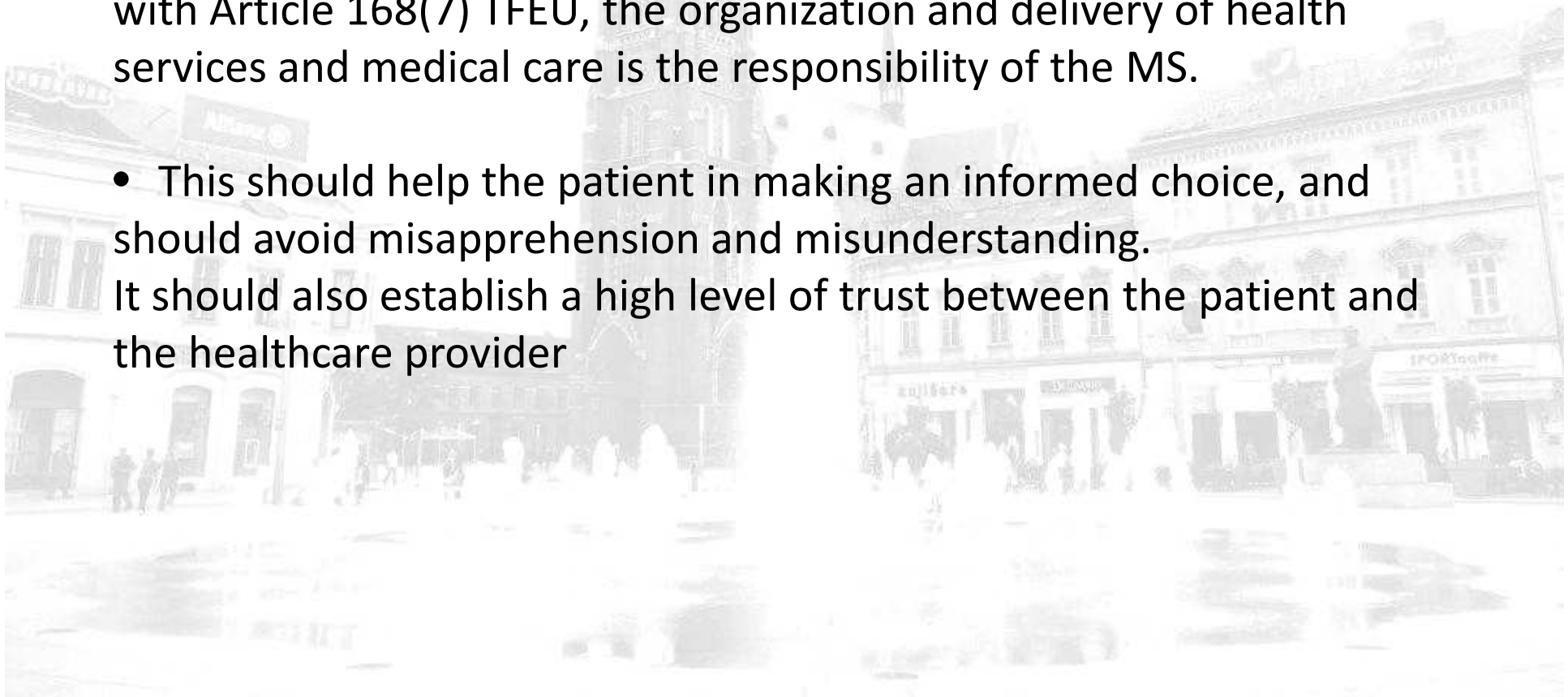


- For the purpose of reimbursing the costs of cross-border healthcare, Directive should cover not only the situation where the patient is provided with healthcare in a MS other than the MS of affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service.

- The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a MS other than the MS of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another MS than that in which the prescription was issued

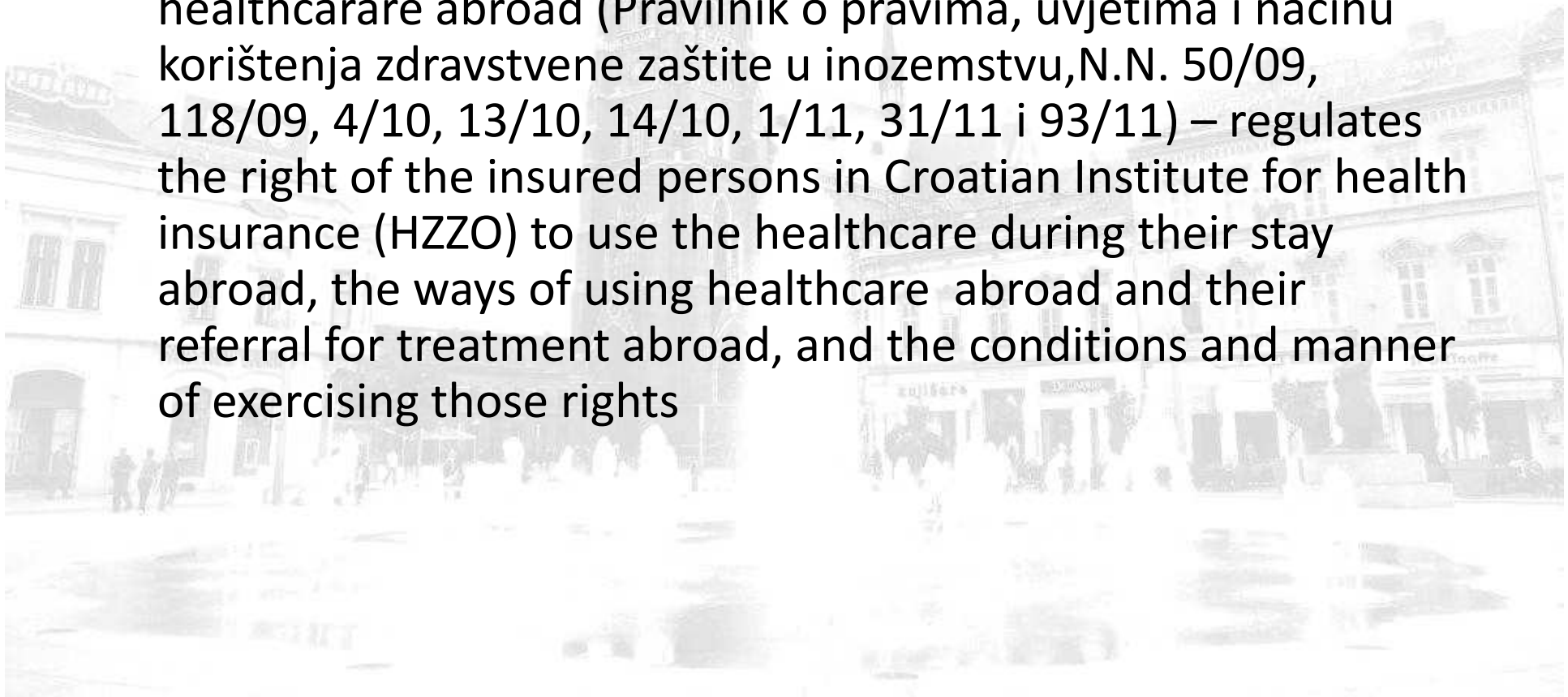


- When a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable.
- The rules applicable to cross-border healthcare should be those set out in the legislation of the MS of treatment, given that, in accordance with Article 168(7) TFEU, the organization and delivery of health services and medical care is the responsibility of the MS.
- This should help the patient in making an informed choice, and should avoid misapprehension and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider



Legal framework in Croatia (right to receive healthcare abroad)

- Compulsory health insurance Act (Zakon o obveznom zdravstvenom osiguranju, N.N. 94/09, 153/09, 71/10, 139/10, 49/11)
- Regulation on rights, conditions and manner of using healthcarare abroad (Pravilnik o pravima, uvjetima i načinu korištenja zdravstvene zaštite u inozemstvu, N.N. 50/09, 118/09, 4/10, 13/10, 14/10, 1/11, 31/11 i 93/11) – regulates the right of the insured persons in Croatian Institute for health insurance (HZZO) to use the healthcare during their stay abroad, the ways of using healthcare abroad and their referral for treatment abroad, and the conditions and manner of exercising those rights



- National procedural rules governing the procedure for granting prior authorization for treatment abroad are actually a restriction of free movement of healthcare services–

(Preamble 38. Directive 2011/24/EU:

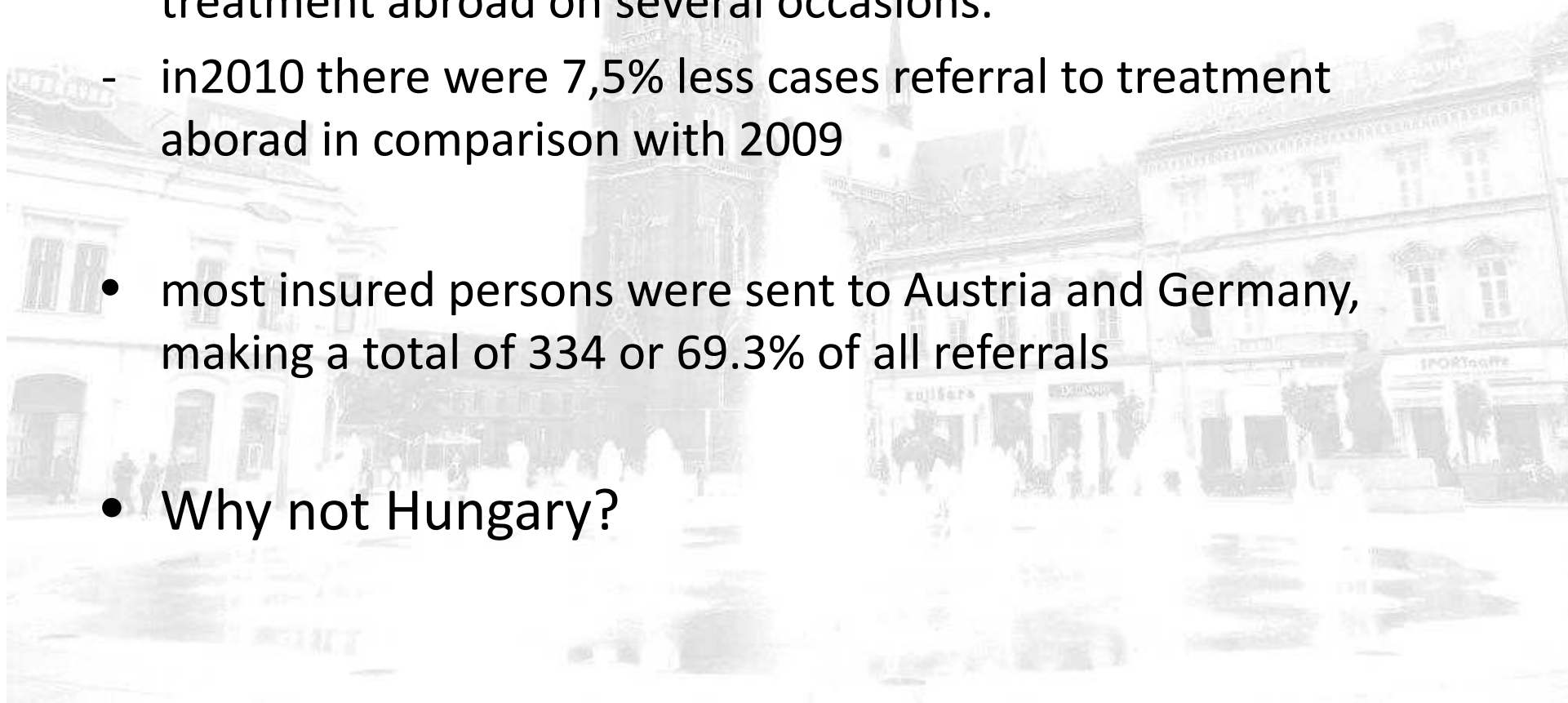
in the light of the case law of the ECJ making the assumption by the statutory social security system or national health system of costs of healthcare provided in another MS subject to prior authorization is a restriction to the free movement of services. MS of affiliation should not make the assumption of the costs of healthcare provided in another MS subject to prior authorization where the costs of that care, if it had been provided in its territory, would have been borne by its statutory social security system or national health system.

European Union:

only 1% of all healthcare services are cross-border services



- HZZO report, March 2011
 - in 2010 - number of realized cases referral to treatment abroad was 482 (521 in 2009), all together there were 333 insured persons referred to treatment abroad (367 in 2009), since some of the insured person was entitled to medical treatment abroad on several occasions.
 - in 2010 there were 7,5% less cases referral to treatment abroad in comparison with 2009
- most insured persons were sent to Austria and Germany, making a total of 334 or 69.3% of all referrals
- Why not Hungary?



- Waiting lists:

Preamble 43 Directive 2011/24

- The refusal to grant prior authorization may not be based on the ground that there were waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment

(<http://www.mzss.hr/zdravstvo> i [socijalna skrb](http://www.mzss.hr/socijalna-skrb)/[nacionalna lista cekanja](http://www.mzss.hr/nacionalna-lista-cekanja))

- Example: Croatian National waiting list (November, 2011)

CT

- Slavonski Brod: 122 days
- Osijek: 70 days

MR (magnetic resonance imaging)

- Slavonski Brod: 296 days

Mammography

- Čakovec: 186 days

Hip endoprosthesis

- Nova Gradiška 960 days





Instead of going to :

Šibenik (CT, no waiting list)

Gospić (MR, 15 days)

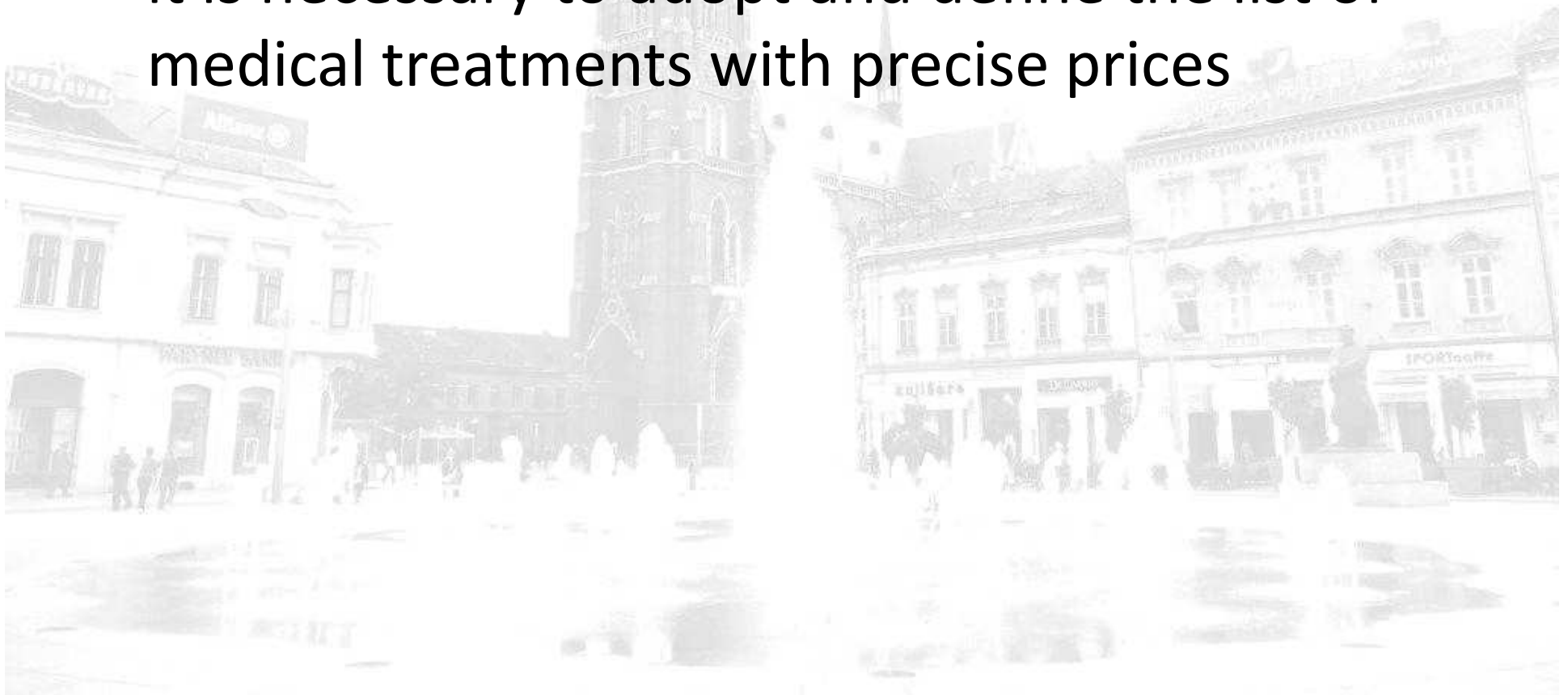
Pula (mamography, no waiting list)

or Šibenik (hip endoprothesis, no waiting list)

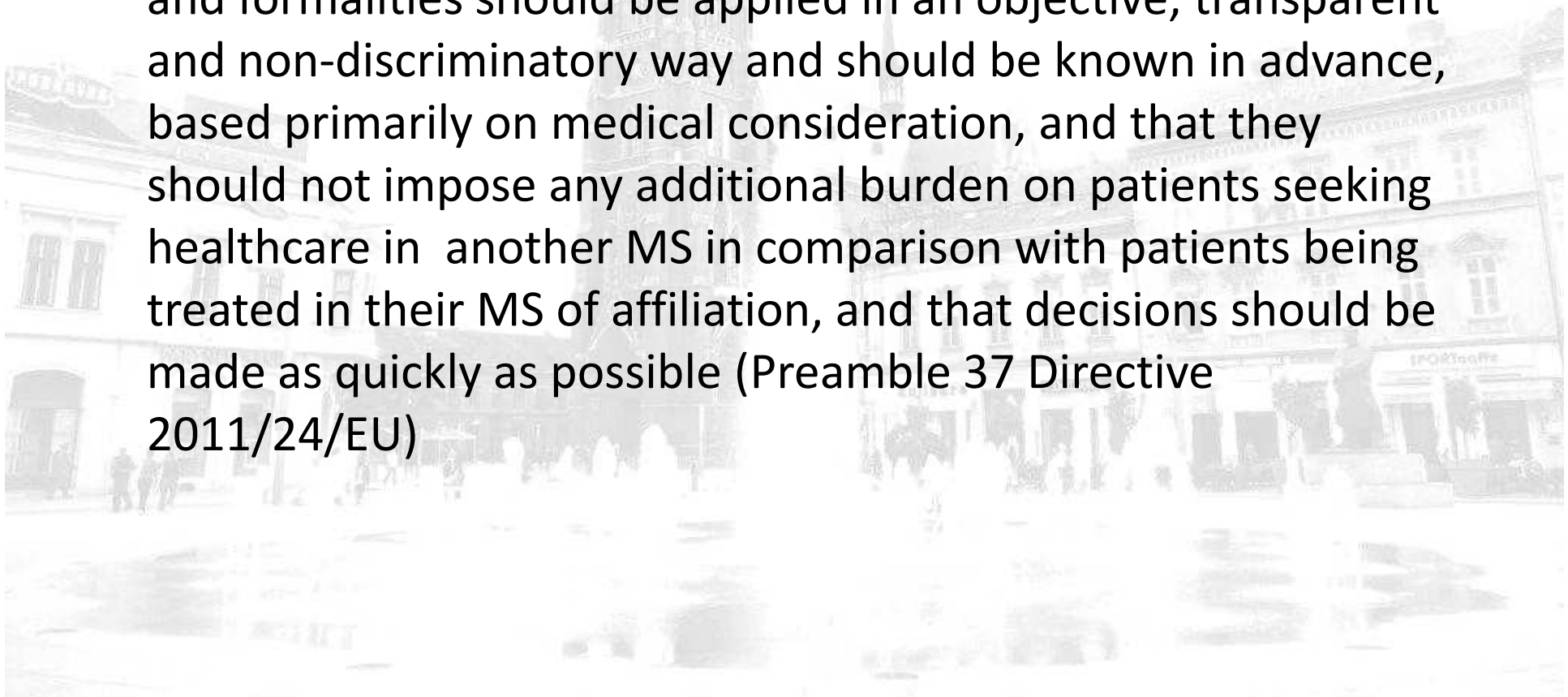
Why not to go to: Kaposvar, Pecs or Szeged ?

In national rules:

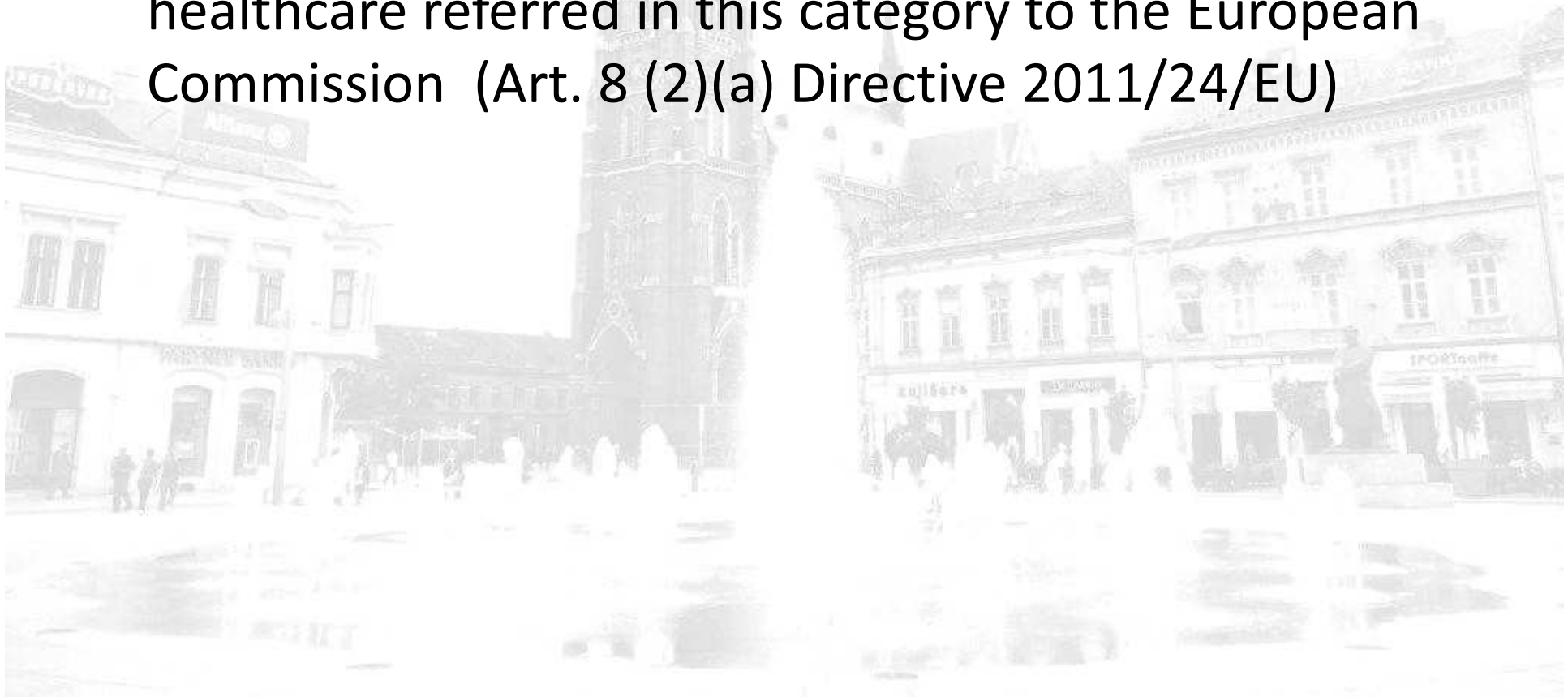
- it is necessary to adopt and define the list of medical treatments with precise prices



- Authorization system is an obstacle to free movement of healthcare services
 - it is appropriate to require that general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical consideration, and that they should not impose any additional burden on patients seeking healthcare in another MS in comparison with patients being treated in their MS of affiliation, and that decisions should be made as quickly as possible (Preamble 37 Directive 2011/24/EU)

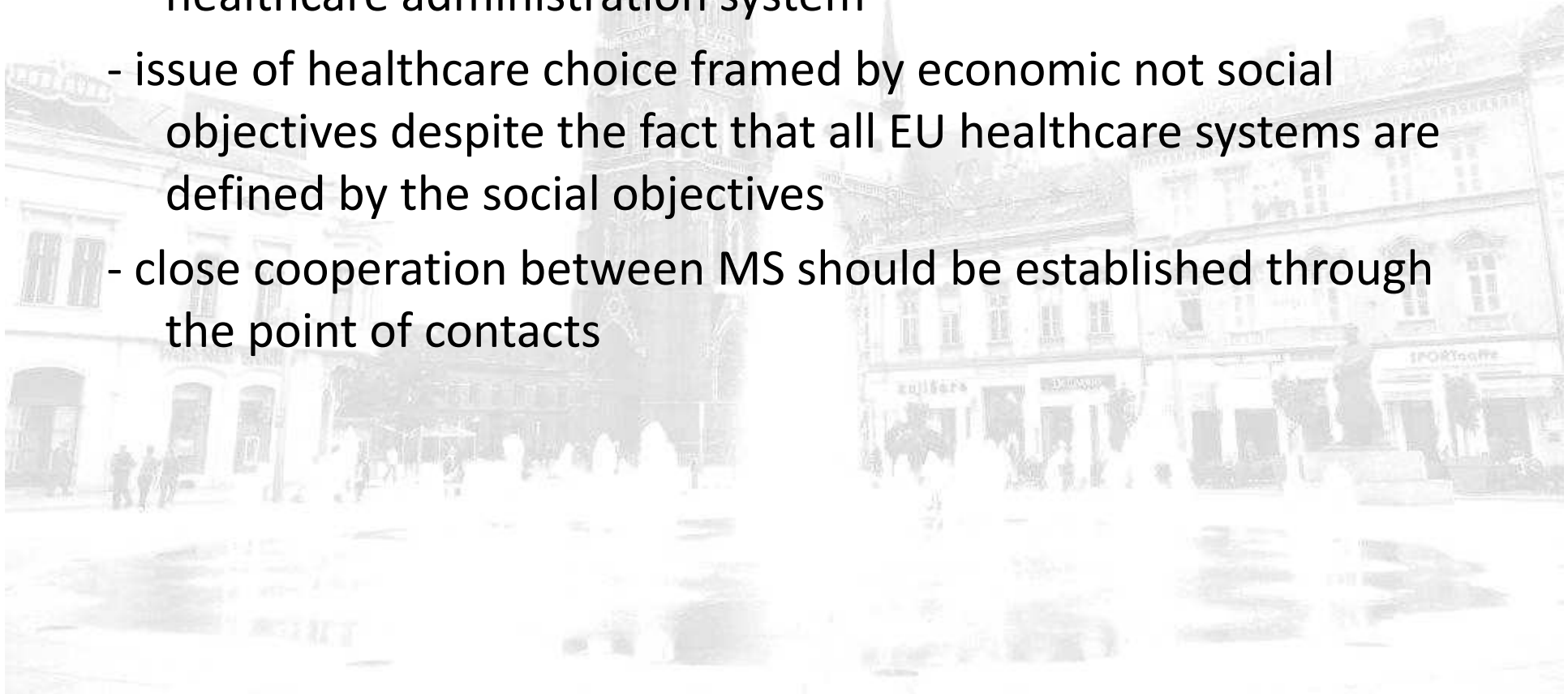


- Healthcare that may be subject to prior authorization shall be limited – MS shall notify the categories of healthcare referred in this category to the European Commission (Art. 8 (2)(a) Directive 2011/24/EU)



Conclusion

- Europeisation of healthcare services have improved patients rights on supranational level, but on the other hand loss of the national boundaries of the national healthcare system
- lot of arising practical problems still remains in national healthcare administration system
- issue of healthcare choice framed by economic not social objectives despite the fact that all EU healthcare systems are defined by the social objectives
- close cooperation between MS should be established through the point of contacts



Thank you for your attention!

