

EU Law on Healthcare professionals: the legal contexts for blood safety

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Keeping up with Reality and Quality: A Challenge for European Blood Establishments Webinars

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Summary

- Introduction
- Concept of 'health professional' in Europe
- Logic of EU's regulation of health professionals – cf national logics
- Place of health considerations in the internal market
- Interpretation and application of EU law on health professionals, especially in an area like blood safety, deferential to national preferences
- Minimum requirements on health professionals in blood safety
- Conclusions



Photo source: <https://www.theparliamentmagazine.eu/news/article/why-europe-needs-a-health-union>

Introduction

- Shared competence between Union and Member States
- 'Pre-emption'
- Sounds simple, but ...
- In effect means field like securing blood quality and safety occupied by legal rules and other norms from national and supra-national levels
- Supra-national measures, eg
 - European Parliament and Council Directive 2002/98/EC (as amended)
 - Commission Directive 2005/62/EC (as amended)
 - Good Practice Guidelines for Blood Establishments Required to Comply with Directive 2005/62/EC

Concept of 'health professional' in Europe

- Covers very diverse range of roles and activities
- From ... to ...
 - Highly specialized, technologically expert, cutting edge services ... near 'social care' roles
 - Member of complex team ... sole practitioner
 - Recognised in all European countries ... recognised in just a few or one
- Lower income and higher income countries
 - Migration patterns complex, not one-way
 - But overall greater opportunities in North/West European states

Logic of EU and national regulation of health professionals

- In general, not the same logic as in domestic domains
- Domestic rationales
 - Correct imbalance of power
 - Protect informed choice of vulnerable patients
 - Protect patients' privacy and bodily integrity
 - Secure ethical practice
 - Protect national health systems (public purse)
 - Population health contributes to
 - National security (eg in a pandemic)
 - Equality
 - Protection of the vulnerable (eg children or elderly adults)
 - Economic growth



Logic of EU and national regulation of health professionals

- European Union rationales
 - Create single European market
 - Foster free movement of health professionals in the EU
 - Efficiencies of scale – could be beneficial to patients
 - But mainly focused on liberalisation of professional movement within the EU
 - In effect supports migrations from East and South of Europe to West and North



Place of health considerations in the EU's internal market

- Article 9 TFEU 'in defining and implementing its policies and activities, the Union shall take into account ... a high level of ... protection of human health'
- Directive 2005/36/EC on mutual recognition of professional qualifications, Article 7 (4)
 - Exception to general rule
 - Qualifications of crossborder providers of health services can be checked by host Member State
 - Reflects special status of health in the internal market, as applied to health professionals
- Health not an 'ordinary consumer service'

Interpretation and application of EU law on health professionals in blood safety domains

- Minimum harmonization legislation – sets a regulatory 'floor'
- Member States may apply higher standards for their domestic contexts *provided* these do not constitute an unjustified restriction on free movement
- Article 168 TFEU – the Union must respect responsibilities of Member States for the definition of their health policy
- Directive 2002/98, Article 4 (2)
 - 'This Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty'
 - Confirmed Case C-512/12 *Octapharma*
- Interpretation and application of EU law to give deference to national preferences

Minimum requirements

- Obligations to provide information about staffing and especially 'responsible persons' to the national competent authority (Article 5 (2); Annex I, Directive 2002/98)
- Obligations to examine potential blood donors
 - 'a qualified health professional' (Article 19, Directive 2002/98)
 - Elaborated Annexes Directive 2004/33 and CoE Guidelines, para 6.1.5
- Obligations to designate a 'responsible person' (Article 9, Directive 2002/98)
 - Ensure compliance with 'the rules in force in the Member State'
 - Reporting obligation
 - Quality management and haemovigilance requirements (Articles 10-15 Directive 2002/98)
 - Permission to delegate (Article 9 (3) Directive 2002/98)

Minimum requirements

- Personnel directly involved with testing, preparation, storage and distribution must be provided with timely, relevant and regularly updated training (Article 10 Directive 2002/98)
- Not clear whether this applies to 'responsible person' if not 'directly involved'
 - May be no legal obligation in EU law here
 - But good practice to ensure aware of state-of-the-art

Minimum requirements

- Structure of EU law and way EU law interacts with national law in health field an important context for interpretation of EU blood safety law, eg Directive 2002/98
- Case C-96/20 *Ordine Nazionale dei Biologi, MX, NY, OZ v Presidenza del Consiglio dei Ministri* lodged with the CJEU in February 2020 asks whether a Member State may require a medical degree in order to be a 'responsible person' under the Directive
- Yes, in my view
 - The Directive sets *minimum* harmonization rules
 - Directive's purpose is to secure blood safety (legal basis now Article 168 TFEU)
 - Purpose is *not* to confer entitlements on individual health professionals
- Thus, Article 9 (2) of the Directive does not confer an enforceable right on a holder of a qualification in the field of biological science to be a 'responsible person' within a blood establishment
 - Member States may adopt a more strict approach than the Directive's minimum 'floor'

Minimum requirements

- Rule applies *so long as the higher standard is compliant with internal market law*
- In principle, any domestic measure restricting cross-border employment, establishment or provision of services (including health services) is a 'suspect' measure, in terms of internal market law
- In principle, therefore, stricter rules in one Member State would make it more difficult for health professionals qualified in another, less strict, Member State, to 'access the market' in the stricter Member State by taking up employment, establishing themselves or offering services as a health professional

Minimum requirements

- But this *in principle* rule is subject to the Member State with the stricter rule being able to offer an *objective justification* for the stricter rule
- In general, an objective justification is subject to strict proportionality control
- But in many areas of health law, this is less so
 - Directive on mutual recognition of professional qualifications allows Member States to control providers of health services who remain established in another Member State
 - Member States may require 'compensating measures' when a health professional not in an 'automatic recognition' profession seeks to work or establish herself in another Member State
 - Member States may require incoming health professionals to take an aptitude test or serve an adaptation period
- Member States thus retain significant control in practice over the regulatory environment pertaining to health professionals offering health services in their territory
- This is also the case in the context of blood safety regulation

Conclusions

- The logics of internal market law do apply to health professionals operating in the blood safety domain
- EU blood regulation establishes a minimum floor
 - Member States may find themselves having to justify higher standards
 - Protecting public health and the national health system are acceptable justifications
- Important to neither over-state, nor under-state, the relevance of EU law to regulation of health professionals in the blood safety domain
 - Member States do not have unfettered powers
 - Member States have not lost all control or discretion

Sources and thanks

- Hervey and McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2005)
- Jean Monnet Network on European Health Law and Policy
- Health Governance after Brexit, Economic and Social Research Council

