



Market-driven deregulation attempts in the European Union

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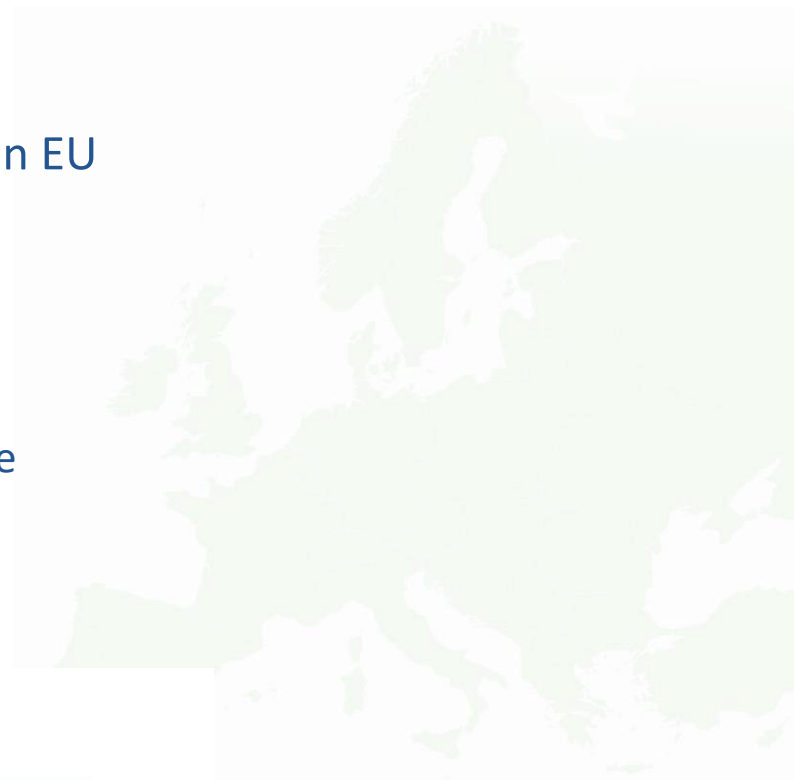
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3. Proportionality Test Directive - Deregulation attempt?
 1. Proportionality principle
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 4. Impact
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1. Setting the scene: Economics vs Health?

Regulation of professions is constantly treated by EU policy makers as an obstacle to the single market that needs to be removed.

- EC has repeatedly challenged MS before **ECJ** with regard to the proportionality of **national pharmacy ownership and establishment rules**
- EU trend towards prioritising **economic and employment growth** (Single Market Objectives)
- Some **examples of de-regulating initiatives** at **DG GROW**:
 - 2006: Services Directive (2006)
 - 2017: Services Package (**Proportionality Test Directive**)
 - 2018: Communication on operational restrictions to retail (including OTCs, alcohol and tobacco)

1. Setting the scene: Economics vs Health?

Other initiatives within Europe:

- **European Commission:** European Semester
- **OECD** – reports on competitiveness making **recommendations** which also affect regulation of professions (**restrictiveness indicators** – e.g. 2015 report: Greek government introduced OTC distribution channel and ownership rules and Italy has introduced ownership liberalisation).
- **National Competition Authorities** – reports in favour of deregulation of professions.

Impact:

- Those countries facing financial/economic instability are more keen on following recommendations from European Semester/OECD and therefore de-regulating some professions.

2. How HCP are regulated in the EU?



- EU Member States are free to decide on the level of protection they wish to grant to public health and the way to achieve such protection.

- Many EU Member States foresee a number of rules on access and exercise of the HCP (reserved activities, compulsory chamber membership, establishment criteria, CPD, language requirements, etc.).



- The Directive on Recognition of Professional Qualifications (RPQD) intends to allow mobility of professionals across EU countries. It focuses on access to the profession (such as title protection).

- On the contrary, the proportionality test directive focuses on exercise of the profession (e.g. reserved activities, establishment rules, code of conduct, CPD, incompatibility rules)

2. Why regulation of HCP is important?

- **European health systems** are continuously ranked among *the top performing in the world* and are recognised for **providing high quality and accessible healthcare services to citizens.**
- Regulation of health professionals serves a clear purpose of ensuring the **highest level of public health protection.**
- By regulating HCP Member States are safeguarding **quality and availability of health care services** (e.g. CPD, codes of ethics, establishment rules, etc.)
- Without regulation of health professions patient safety may be put at a risk – we have seen this to happen in certain countries



3.1 Proportionality principle

- The **fundamental freedoms of the TFEU apply to the regulation of healthcare services**, in particular:
 - regulation governing access to national health services market; and
 - regulation governing the exercise of the health care activity itself.
- But, Member States are allowed to maintain **barriers to free movement provided that these are justified in the public interest.**
- Restrictive measures would be justified if they:
 - are necessary to protect the public interest objective;
 - do not exceed what is necessary to attain this objective; and
 - the objective cannot be achieved by a less restrictive measure.



3. 2 Proportionality Test Directive - Context

- Services Directive
 - Explicit exclusion of health care services from its scope
- EU Single Market Strategy (economic growth and increasing jobs)
- **RPQD** introduced a **mutual evaluation exercise** (MS to do **National Action Plans**)
- **Services Package**
 - E-card
 - Notification procedure
 - **Proportionality (access and exercise of the profession for the first time in a legislative measure) – *currently awaiting forma adoption by EU legislator***
 - Recommendations on a number of professions

3.3 Proportionality Test - new obligations

- 1 Explanation justifying the need and the proportionality of regulation of professions before adoption
- 2 Objective and independent analysis of the reasons (qualitative and where possible and relevant quantitative elements)
- 3 Monitoring the proportionality of regulation after adoption taking account of new developments
- 4 MS should verify a specific list of criteria before adopting any regulation

3.3 Proportionality test – List of Criteria

Nature of the risks to individuals related to the public interest objectives;

The suitability of the provision to address the risk identified;

Impact on free movement of persons and services, on consumer choice and quality of the service;

Assess the effect of combining new and existing requirements:

- a) reserved activities and protected professional title;
- b) CPD requirements;
- c) Codes of ethics and supervision rules
- d) compulsory chamber membership, registration or authorisation schemes,
- e) quantitative restrictions
- f) Territorial restrictions
- g) Legal form requirements and ownership rules;
- h) Language requirements.

3.3 Proportionality test - Specific provisions for public health and HCP

Public health deserves a high level of protection and health professions differ from other professions with no patient safety implications

Regulation of HCP should contribute to guaranteeing access to healthcare as well as to safe, high quality and efficient healthcare to citizens

high quality of service, adequate and safe supply of medicinal products, in accordance with the public health needs in the territory of the Member State concerned,

Professional independence and reserved activities is justified for HCP

3.3 General provisions introducing a minimum flexibility

1.

Member States should remain competent to decide whether and how to regulate a profession (*margin of discretion*)

2.

The extent and level of detail of the assessment will depend on the nature, content and impact of the provision being introduced

3.

Additional requirements may be suitable or even positive, for instance **CPDs** or **compulsory chamber membership** but also **ownership rules**

3.4 Proportionality Test Directive – Impact on HCP

New obligations for Member States each time they wish to regulate or modify existing regulation of a profession **before even adopting it.**

Proportionality assessment will be more **cumbersome** for national authorities and may create **uncertainty.**

How can we provide qualitative or quantitative elements to justify **precautionary measures** in the context of HCP regulation?

Directive to be implemented by Member States (2 years period): involvement of Health Ministries in correctly transposing the relevant provisions is key to ensure Member States can still protect human health through regulation of HCP.

5. Conclusions and Challenges



Are economy and growth replacing public health as a public interest?

Will the Proportionality Test Directive have a regulatory chill/deregulation effect?

Advocacy vis-à-vis EU institutions and Member States is key (e.g. national implementation of Proportionality Test Directive)

We cannot stop deregulation of health professions but we can work for mitigating measures to be put in place.

How the Proportionality Directive will apply to regulation of HCP?

WHAT IS NEXT?

Ultimately, it will be up to the **Court of Justice** to interpret how the proportionality directive applies to specific regulation of HCP.



Court of Justice until now quite positive (precautionary principle, establishment and ownership rules were found justified and proportionate) BUT...





Will the Court of Justice continue applying its lenient approach to HCP or would it rather follows the stricter approach taken in the Parkinson case where it concluded the parties did not provide sufficient evidence to justify pricing rules of prescription medicines in Germany?



THANK YOU!



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