

## CPME Members' Briefing

13 March 2019

# 'Proportionality Directive'

## Background, processes, impact

### What this briefing is for

This briefing is to provide CPME members with the background information and relevant details on [Directive \(EU\) 2018/958 of the European Parliament and of the Council of 28 June 2018 on a proportionality test before adoption of new regulation of professions \('Proportionality Directive'\)](#).

The objective is to facilitate CPME members' contribution to the implementation process and application of the legislation in future, as relevant.

### Key points

- What is the Proportionality Directive?
- What is 'proportionality'?
- How will the Proportionality Directive work?
- What does the Proportionality Directive mean for the CPME members?
- How can CPME members become involved in the implementation process?
- What are the most relevant arguments for adopting a tailored approach for doctors' regulation?

### What is the Proportionality Directive?

At EU-level, the [Directive on the recognition of professional qualifications 2005/36/EC \('Professional Qualifications Directive'\)](#) regulates certain features of doctors' access to or practice of their profession, such as minimum training conditions. All other access and practice requirements for the medical profession are in principle a competence of Member States. Rules on reserved activities, codes of ethics or fee schedules for example, are all made at national level. However, these national rules can also affect other right EU law grants professionals, in particular their right to pursue a



profession, in a self-employed or employed capacity, in a Member State other than the one in which they have obtained their professional qualifications. Under EU law, these rights cannot be restricted without justification, i.e. any regulations restricting these rights need to be 'proportional'. To enable a full check of the proportionality of national provisions affecting access to or exercise of a regulated profession in terms of their compliance with EU law, the Proportionality Directive was adopted.

The [Proportionality Directive](#) obliges Member States to carry out a proportionality assessment before introducing new or revising existing national legislative, regulatory or administrative provisions affecting access to or exercise of a regulated profession. The aim is to ensure that any such provisions are conclusively justified and the least restrictive possible as regards the risk that should be mitigated. The ulterior objective is to facilitate (cross-border) market access for new professionals, improve labour mobility and hence economic growth. The requirement to carry out a proportionality assessment was already established in the [Professional Qualifications Directive](#). At the same time case law of the European Court of Justice (EJC) on the proportionality of professional regulation set out principles which Member States must consider, please find a compilation [here](#). Structured proportionality assessments are also often already part of the national legislative process, testing for example the necessity and suitability of a new law. The innovation the Proportionality Directive brings is the introduction of detailed and explicit common EU-level framework harmonising the elements the proportionality assessment should comprise to comply with EU law.

## What is 'proportionality'?

Proportionality is a general principle of EU law, which follows from the European Court of Justice's case law. It requires Member States to strike the right balance between preserving the fundamental freedoms guaranteed by the Treaty (such as the freedom to provide services) and Member States' margin of discretion to decide on how to protect a public interest objective (such as public health)<sup>1</sup>.

The European Court of Justice defines this balance as follows:

*"National measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty must fulfil four conditions:*

- *they must be applied in a non-discriminatory manner;*
- *they must be justified by imperative requirements in the general interest;*
- *they must be suitable for securing the attainment of the objective which they pursue;*
- *and they must not go beyond what is necessary in order to attain it"*<sup>2</sup>.

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<sup>1</sup> See Article 5(4) of the Treaty of the European Union (TEU) and Protocol No. 2.

<sup>2</sup> Gebhardt, C-55/94, paragraph 37 and paragraph 6 of the judgement.



Proportionality is also a common general principle enshrined in national constitutions and laws of the Member States, though the respective conditions may differ in certain details.

## How will the Proportionality Directive work?

Member States must in future apply an ex ante proportionality assessment of new provisions or regulatory reforms restricting the access to or exercise of a regulated profession. This also applies if a Member State has delegated the competence to adopt such regulations to a professional body, such as a national medical association.

### 1. Scope of the Proportionality Directive

To decide if the Proportionality Directive is relevant to a new provision or a regulatory reform, Member States must check if the following applicability conditions are met:

- The provision in question concerns a regulated profession falling under the scope of the Professional Qualifications Directive. Doctors of medicine are always within the scope.
- The provision in question restricts the access to or pursuit of that regulated profession.
- The provision in question is more than an editorial amendment, technical adaptation to the content of training courses or the modernisation of training regulations.
- The provision in question is not a direct result of specific EU legislation which requires a strict transposition by Member States.

→ **If the answer to any of these conditions is no, the Proportionality Directive does not apply.**

### 2. Procedure for proportionality assessments

If these conditions are met, Member States must take into account the following procedural requirements:

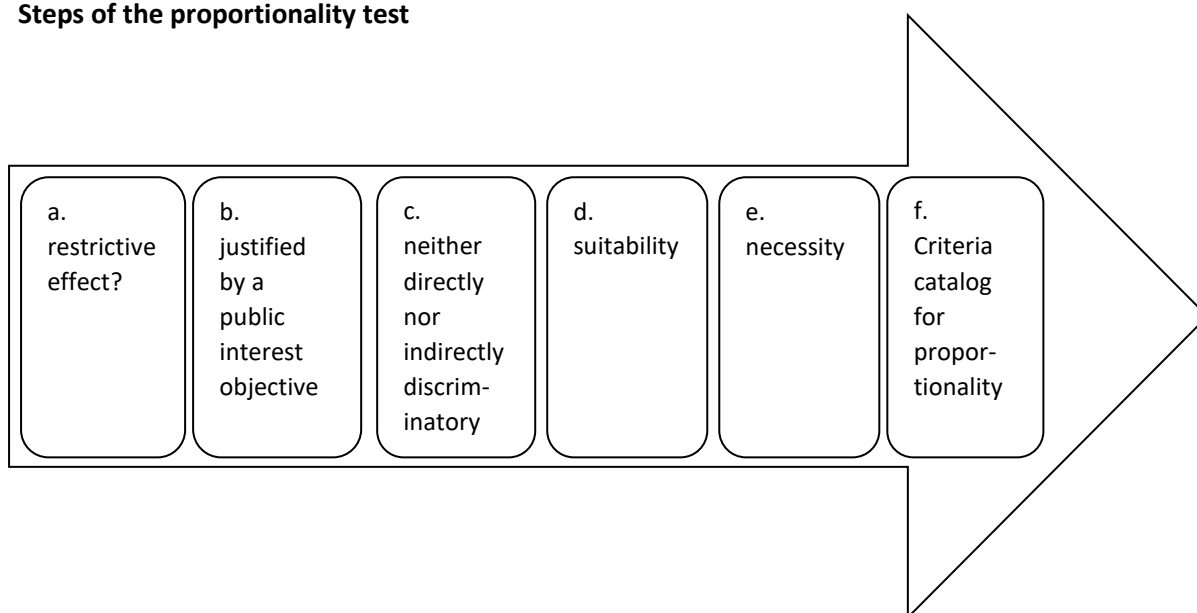
- Adapt the proportionality assessment to be itself proportional to the extent of the nature, content and impact of the provision in question;
- Ensure information and involvement of stakeholders, including the opportunity for all parties involved to present their views on the provisions in question;
- Support the justification of the public interest objectives (see further details below) pursued by the provisions in question by an objective analysis, including qualitative and, wherever possible and relevant, quantitative elements which however need not be specific studies;
- Ensure the objectivity and independence of the proportionality assessment, which could include requesting an independent body (such as regulatory scrutiny board) to be involved, in particular if i.a. a professional body is responsible for the regulatory reform;
- Submit the proportionality assessment including justifications and any supporting documents to the European Commission via the screening form of the public RegProf database of the Internal



Market Information system, as is already required for national competent authorities under the Professional Qualifications Directive;

- Establish a monitoring process for the regular ex post review of adopted provisions to ensure the proportionality assessment appropriate, e.g. in view of new scientific and technological developments.

### 3. Steps of the proportionality test



#### a. Restrictive effect of provisions

- The proportionality assessment is applicable to new provisions or regulatory reforms which concern the following requirements:
  - *Practice and access restrictions*: protection of professional titles; reserved activities (both exclusive and shared by several professions); rules relating to the organisation of the profession, professional ethics and supervision; requirements on professional liability insurance or protection; compulsory registration with or membership of a chamber, professional body or state body
  - *Competency requirements*: qualification requirements to be able to exercise reserved activities; obligations to undergo continuing professional development; language knowledge requirements



- *Quantitative restrictions*: limits on volume of licences granted to exercise a profession; minimum or maximum limits on number of employees, managers or others holding certain professional qualifications; territorial restrictions on licences to practice, e.g. for establishment in a certain geographic region; age restrictions
  - *Legal form requirements*: requirements relating to a specific legal form; requirements affecting shareholding, management or voting rights requirements where linked to exercise of profession; restrictions on joint exercise of profession or partnership; incompatibility rules; fixed minimum or maximum tariffs; advertising restrictions
  - *Authorisation requirements*: authorisation requirements beyond notified requirements such as check of criminal records, financial standing; authorisations for exercise of specific activities within professional practice
- Where a new provision or regulatory reform relates to the temporary or occasional provision of services as defined by the Professional Qualifications Directive, the following requirements are also subject to a proportionality assessment:
    - *Prior declaration*: mandatory prior declaration; documents accompanying a mandatory prior declaration
    - *Requirements on fees*: levy of fees for administrative procedures relating to prior declaration

**b. Regulation is justified by a public interest objective**

- Member States must ensure that legislative, regulatory or administrative provisions restricting access to, or the pursuit of, regulated professions are justified by a public interest objective.

*Public interest objective*

There are aims which are recognised as public interest objectives under EU law including public health, as set out in Article 6(1) of the Proportionality Directive. Furthermore, EU law recognises overriding reasons in the public interest including the financial equilibrium of social security systems, or social policy objectives.

As regards public health, the Treaty on the Functioning of the European Union (TFEU) in Article 168(1) additionally provides that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. This is also reflected in Article 7(5) of the Proportionality Directive which makes explicit that provisions concerning the regulation of healthcare professions and with patient safety implications require Member States to take into account the objective of ensuring a high level of human health protection.



To invoke the protection of public health as a justification for a regulatory reform, it is thus necessary to establish a causal link between the provision in question and the objective of protecting public health, such as the identification of patients as the beneficiaries of the provision (see annex for examples).

- Member States must test planned regulatory reforms as to whether these are non-discriminatory, necessary and suitable for securing the attainment of the objective which they pursue and do not go beyond what is necessary to attain that objective.

#### **c. Non-discrimination**

Non-discrimination is a general principle of EU law and refers to the need to exclude both direct and indirect discriminatory on the basis of nationality or residence. This includes

*“not only overt discrimination by reason of nationality but also all covert forms of discrimination which, by the application of other distinguishing criteria, lead in fact to the same result [...]. Accordingly, conditions imposed by national law must be regarded as indirectly discriminatory where, although applicable irrespective of nationality, they affect essentially migrant workers [...] or the great majority of those affected are migrant workers [...], where they are indistinctly applicable but can more easily be satisfied by national workers than by migrant workers [...] or where there is a risk that they may operate to the particular detriment of migrant [...].”<sup>3</sup>*

#### **d. Regulations are suitable for securing the attainment of the objective pursued**

Member States must justify the suitability of a regulatory reform by demonstrating that a provision has considered the following:

- the nature of the risks related to the public interest objectives pursued, in particular the risks to service recipients;
- the degree to which professional regulation is consistent and systematic, e.g. if it addresses risks in a similar way in comparable activities;
- the asymmetry of information between the professional and the service recipients, as well as the impact of scientific or technological developments which may increase or decrease this asymmetry
- the impact on the free movement of persons and services within the Union, on consumer choice and on the quality of the service provided.

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<sup>3</sup> O'Flynn, [C-237/94](#), paragraphs 17 and 18 of the judgment



#### **e. Necessity**

Member States must justify the necessity of a regulatory reform by demonstrating that a provision has considered the following:

- the possibility of using less restrictive means to achieve the public interest objective, such as existing rules of a specific or more general nature, e.g. consumer protection laws, in particular with regard to reserved activities;
- the effect of new or amended provisions, when combined with others and whether they are necessary for the achievement of the same public interest objective.

#### **f. Criteria catalogue for proportionality**

##### ▪ *Criteria for assessing the proportionality*

For the proportionality test, Article 7 (2) paragraph 1 (a)-(f) sets out a set of criteria which Member States must take into account:

- the nature of the risks related to the public interest objectives pursued;
- whether existing rules of a specific or more general nature are insufficient for the attainment of the objective pursued;
- whether the provision genuinely reflects the objective in a consistent and systematic manner and thus addresses the risks identified in a similar way as in comparable activities;
- the impact on the free movement of persons and services within the Union, on consumer choice and on the quality of the service provided;
- the possibility of using less restrictive means to achieve the public interest objective;
- the effect of new or amended provisions, when combined with other provisions restricting access to, or the pursuit of, the profession.

##### ▪ *Additional criteria*

According to Article 7 (2) paragraph 2 (a)-(f), Member States should consider additional criteria which are relevant for the regulated profession being analysed:

- the connection between the scope of activities covered by a profession or reserved to it and the professional qualification required;
- the connection between the complexity of the tasks concerned and the need for those carrying them out to possess specific professional qualifications, in particular as regards the level, the nature and the duration of the training or experience required;
- the possibility of obtaining the professional qualification by alternative routes;



- the degree of autonomy in exercising a regulated profession and the impact of organisational and supervision arrangements on the attainment of the objective pursued, in particular where the activities relating to a regulated profession are pursued under the control and responsibility of a duly qualified professional;
- whether, and why, the activities reserved to certain professions can or cannot be shared with other professions;
- the scientific and technological developments which may effectively reduce or increase the asymmetry of information between professionals and consumers.

The European Commission indicates that the criteria relating to the connection between scope of reserved activities and professional qualification, complexity of tasks, and autonomy of profession are expected to be addressed in particular for provisions on reserved activities (see annex). However, this does not mean that reserved activities will be deemed disproportionate. In fact, it is acknowledged in Recital 24 of the Proportionality Directive that “Regulation by way of reserved activities and protected professional title should be considered where the measures aim to prevent a risk of serious harm to public interest objectives, such as public health.”, thus confirming Member States’ discretion in this matter.

▪ *Combination with existing requirements*

Article 7 (3) is a special provision for cases in which Member States introduce a new regulation on a regulated profession or amend existing provisions combined with one or more requirements for the profession. The taking-up and pursuit of certain activities may be conditional on complying with several requirements such as rules relating to

- the organisation of the profession,
- compulsory membership of a professional organisation or body,
- professional ethics,
- supervision
- and liability.

Therefore, when assessing the effect of the new or amended provisions, Member States should take into account the existing requirements, including

- continuous professional development,
- compulsory membership of a professional organisation or body,
- registration or authorisation schemes,
- quantitative restrictions,
- specific legal form requirements and shareholding requirements,
- territorial restrictions,



- multidisciplinary restrictions and incompatibility rules,
- requirements concerning insurance cover,
- language knowledge requirements, to the extent necessary to practise the profession,
- fixed minimum and/or maximum tariff requirements
- and requirements on advertising.

#### 4. Legal review of proportionality assessments

Despite the notification to and check by the European Commission, the ultimate legal assessment of the proportionality of a provision under EU law can only still be made if a provision is subject of a ruling by the European Court of Justice. In accordance with Article 9 of the Proportionality Directive, national courts will also be able to rule on the proportionality of a provision.

### What does the Proportionality Directive mean for the CPME members?

CPME members are affected in the following ways:

- The Proportionality Directive requires Member States to ensure stakeholder information and involvement in the preparation of new or revisions to professional regulation. This is an opportunity for national medical associations to contribute to such processes and comment on the evidence base behind reforms.
- A faulty transposition or application of the proportionality assessment at national level could lead to 'false positives', i.e. national regulators apply the test and conclude that a planned regulatory reform would be deemed disproportionate and therefore abandon it. Similarly, there is the danger of 'regulatory chill', i.e. the postponing or cancellation of regulatory reforms due to a lack of political will to invest the resources into carrying out a proportionality test. If this affects necessary reforms, a lack thereof could have a detrimental effect on doctors and national medical associations.
- National medical associations who act as regulators will in future have to make a proportionality assessment to new or revisions of existing regulation, in accordance with the national transposition of the Proportionality Directive.

### How can CPME members become involved in the implementation process?

The Proportionality Directive must be transposed into national law by 30 July 2020. National medical associations are encouraged to contact the ministries responsible for the transposition process to highlight the need for a tailored approach for the medical profession. As set out, the Proportionality



Directive acknowledges the safeguards that EU law provides for the protection of public health. Member States therefore have considerable discretion to ensure the proportionality assessment for doctors' regulation is calibrated accordingly. Please see below for an overview of the relevant provisions in the Proportionality Directive. In the annex, you can also find a guidance published by the European Commission for the Group of Coordinators illustrating its expectations for proportionality assessments.



## What are the most relevant arguments for adopting a tailored approach for doctors' regulation?

| Argument   | Relevant ECJ case law   | Relevant provision in Proportionality Directive  |
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| <p><b>The protection of human life and health is a primary objective of EU law.</b></p> <p>→ The regulation of health professions has direct bearing on human health and life, the protection of which is a primary objective of EU law.</p> | <p>"When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty. [...]."</p> <p><i>Joined Cases C-171/07 &amp; C-172/07 Apothekerkammer des Saarlandes, paragraph 19</i></p> | <ul style="list-style-type: none"> <li>Recital 19: "With regard to the protection of public health, according to Article 168(1) TFEU, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. This Directive is fully in line with that objective."</li> <li>Recital 30: "As confirmed by settled case-law, the health and life of humans ranks foremost among the interests protected by the TFEU. Consequently, Member States should duly take account of the objective of ensuring a high level of human health protection when assessing requirements for healthcare professions, such as reserved activities, protected professional title, continuous professional development or rules relating to the organisation of the profession, professional ethics and supervision, while respecting the minimum</li> </ul> |



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|  |  | <p>training conditions, laid down in Directive 2005/36/EC. Member States should in particular ensure that the regulation of healthcare professions, having public health and patient safety implications, is proportionate and contributes to the guaranteeing of access to healthcare, recognised as a fundamental right in the Charter, as well as to safe, high quality and efficient healthcare for citizens on their territory. In establishing policies for healthcare services, account should be taken of the need to ensure accessibility, a high quality of service, and an adequate and safe supply of medicinal products, in accordance with the public health needs in the territory of the Member State concerned, as well as of the need to ensure the professional independence of healthcare professionals. With regard to the justification for the regulation of healthcare professions, Member States should take into account the objective of ensuring a high level of human</p> |
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|   |  | <p>health protection, including accessibility and high quality of healthcare for citizens, and adequate and safe supply of medicinal products, taking into consideration the margin of discretion referred to in Article 1 of this Directive.”</p> <ul style="list-style-type: none"> <li>Article 7 (5): “Where provisions referred to in this Article concern the regulation of healthcare professions and have patient safety implications, Member States shall take account of the objective of ensuring a high level of human health protection.”</li> </ul> |
| <p><b>The protection of health justifies restrictions on free movement.</b></p> <p>→ In the regulation of health professions, there are numerous overriding reasons in the public interest which have been acknowledged by case law as justifying restrictions on the freedom to provide services, ranging from the protection of public health to the protection of the dignity of the profession.</p> | <p>“It must be noted, in that regard, that the protection of the health is one of the objectives which may be regarded as overriding reasons in the public interest capable of justifying a restriction on the freedom to provide services (see, to that effect, judgments of 10 March 2009, Hartlauer, C-169/07, EU:C:2009:141, paragraph 46, and of 12 September 2013, Konstantinides, C-475/11, EU:C:2013:542, paragraph 51).</p> | <ul style="list-style-type: none"> <li>Recital 17: “Where the taking-up and the pursuit of employed or self-employed activities are conditional on complying with certain requirements relating to specific professional qualifications, laid down directly or indirectly by the Member States, it is necessary to ensure that such requirements are justified by public interest objectives, such as those within the meaning of the TFEU, namely public policy, public security and public health, or by overriding reasons in</li> </ul>                      |



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|   | <p>In addition, with regard to the importance of the relationship of trust which must prevail between a dentist and his patient, the protection of the dignity of the profession of dentist may also be regarded as being capable of constituting such an overriding reason in the public interest.”</p> <p><i>Case C-339/15 Vanderborght, paragraphs 67 and 68</i></p>   | <p>the public interest, recognised as such in the case-law of the Court of Justice.</p> <ul style="list-style-type: none"> <li>Article 6 (2): “Member States shall consider in particular whether the provisions referred to in paragraph 1 are objectively justified on the basis of public policy, public security or public health, or by overriding reasons in the public interest, [...]”</li> </ul> |
| <p><b>The precautionary principle warrants the regulation of health professions including in cases in which evidence is scarce.</b></p> <p>→ Regulating health professions has direct impact on quality and safety of healthcare. Therefore action can be taken without conclusive evidence on the effects of regulation, in line with the precautionary principle, as confirmed by case law.</p> | <p>“Furthermore, where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective (see Gowan Comércio Internacional e Serviços, paragraph 78 above, paragraph 76 and the case-law cited).”</p> | <p>Not addressed</p>  |



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|   | <i>T-333/10 Animal Trading Company (ATC) BVK, paragraph 81</i>  |   |
| <p><b>The protection of health allows for regulation to occur before risks materialise.</b></p> <p>→ To protect health, case law acknowledges that it is justified to regulate health professions without waiting for risks of non-regulation to materialise.</p> | <p>“Furthermore, it is important that, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. In particular, a Member State may take measures that reduce, as far as possible, a health risk, including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public (see Apothekerkammer des Saarlandes and Others, paragraph 30, and Blanco Pérez and Chao Gómez, paragraph 74).”</p> <p><i>Joined Cases C-159/12 to C-161/12 Venturini, paragraph 60</i></p> | <p>Relevant provisions:</p> <ul style="list-style-type: none"> <li>▪ Recital 13: “[...] Although a Member State does not necessarily have to produce a specific study or a specific form of evidence or materials establishing the proportionality of such a measure prior to its adoption, it should carry out an objective analysis, taking into account the specific circumstances of that Member State, that demonstrates that there are genuine risks for the achievement of public interest objectives.”</li> <li>▪ Recital 20: “[...] Where a Member State intends to regulate a profession or to amend existing rules, account should be taken of the nature of the risks related to the public interest objectives pursued, in particular the risks to service recipients, including consumers, to professionals or to third parties. [...]”</li> <li>▪ Recital 24: “[...] Regulation by way of reserved activities and protected</li> </ul> |



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|  |  | <p>professional title should be considered where the measures aim to prevent a risk of serious harm to public interest objectives, such as public health.”</p> <ul style="list-style-type: none"> <li>▪</li> </ul>  |
| <p><b>Member States have the competence to organise their healthcare systems.</b></p> <p>→ In the regulation of health professions, Member States have discretion.</p> | <p>“None the less, the Court notes that it is for the Member States to decide on the degree of protection which they wish to afford to public health and on the way in which that protection is to be achieved. Since the level may vary from one Member State to another, Member States should be allowed a margin of discretion (see, to that effect, Apothekerkammer des Saarlandes and Others, paragraph 19, and Blanco Pérez and Chao Gómez, paragraph 44).”</p> <p><i>C-539/11 Ottica New Line di Accardi Vincenzo, paragraph 44</i></p> | <ul style="list-style-type: none"> <li>▪ Article 1: “This Directive lays down rules on a common framework for conducting proportionality assessments before introducing new, or amending existing, legislative, regulatory or administrative provisions restricting access to, or the pursuit of, regulated professions, with a view to ensuring the proper functioning of the internal market, while guaranteeing a high level of consumer protection. It does not affect the Member States’ competence, in the absence of harmonisation, and margin of discretion to decide whether and how to regulate a profession within the limits of the principles of non-discrimination and proportionality.”</li> </ul> |
| <p><b>Different national approaches to regulating health professions are explicitly permitted by EU</b></p>  | <p>“[...] when assessing whether the principle of proportionality has been observed in the field</p>   | <ul style="list-style-type: none"> <li>▪ Recital 18: “It is for the Member States to determine the level of protection which they</li> </ul>  |



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| <p><b>law.</b></p> <p>→ Health professions may be subject to different degrees of regulation, as it is in the Member States' competence to assess how to protect public health. Case law confirms that this does not imply that different approaches, e.g. cumulative requirements, are disproportionate per se.</p> | <p>of public health, account must be taken of the fact that a Member State has the power to determine the degree of protection which it wishes to afford to public health and the way in which that degree of protection is to be achieved. Since that degree of protection may vary from one Member State to the other, Member States must be allowed discretion (see, to that effect, Case C-41/02 Commission v Netherlands [2004] ECR I-11375, paragraphs 46 and 51) and, consequently, the fact that one Member State imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate (Case C-262/02 Commission v France, paragraph 37, and Case C-443/02 Schreiber [2004] ECR I-7275, paragraph 48)."</p> <p><i>C-141/07 Commission v Germany (hospital pharmacies), paragraph 51</i></p> | <p>wish to afford to the public interest objectives and the appropriate level of regulation, within the limits of proportionality. The fact that one Member State imposes less strict rules than another Member State does not mean that the latter Member State's rules are disproportionate and therefore incompatible with Union law."</p> <ul style="list-style-type: none"> <li>▪ Article 1: "This Directive lays down rules on a common framework for conducting proportionality assessments before introducing new, or amending existing, legislative, regulatory or administrative provisions restricting access to, or the pursuit of, regulated professions, with a view to ensuring the proper functioning of the internal market, while guaranteeing a high level of consumer protection. It does not affect the Member States' competence, in the absence of harmonisation, and margin of discretion to decide whether and how to regulate a profession within the limits of the principles of non-discrimination and</li> </ul> |
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|  | <p>“In addition, it must be recalled that rules of a Member State do not constitute a restriction within the meaning of the FEU Treaty solely by virtue of the fact that other Member States apply less strict, or economically more favourable, rules to providers of similar services established in their territory (see Commission v Italy, paragraph 49 and the case-law cited).”</p> <p><i>C-475/11 Konstantinidis, paragraph 47</i></p> <p>“When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States must be allowed discretion (see, to this effect, Case</p> | <p>proportionality.”</p> |
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|  | <p>C- 322/01 Deutscher Apothekerverband [2003] ECR I-14887, paragraph 103; Case C-141/07 Commission v Germany [2008] ECR I-0000, paragraph 51; and Hartlauer, paragraph 30)."</p> <p><i>Joined Cases C-171/07 &amp; C-172/07 Apothekerkammer des Saarlandes, paragraph 19</i></p> |  |
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| Additional arguments  |  |
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| <p><b>The economic drivers of the Directive are not compatible with health services.</b></p> <p>→ The Proportionality Directive forms part of the 'Services Package' and reflects both in rationale and approach the economic objectives of the Services Directive. This is not compatible with the rationale of regulating health professions, which is why health professions' services are exempted from the Services Directive.</p> | <p>"A deeper and fairer internal market is a top priority of the Commission: "to put policies that create growth and jobs at the centre of the policy agenda". [...] There is considerable potential to enhance the creation of growth and jobs by Member States through increasing the transparency of their regulated professions and completing a more thorough analysis of their proportionality before adopting any new rules while simultaneously completing reforms in their regulated professions to modernise their requirements. As described in the impact assessment accompanying this proposal, numerous studies show how poor regulatory choices are liable to distort competition by restricting market entry and thus may result in substantial lost employment opportunities, higher prices for consumers</p> |



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|   | <p>and hinder free- movement. In terms of job creation alone, an academic study suggests around 700 000 more jobs could be created in the EU through addressing unnecessary and disproportionate regulations.”</p> <p><i>Explanatory memorandum of proposal for a Directive on a proportionality test before adoption of new regulation of professions</i></p>   |
| <p><b>There is no robust evidence on the effects of (de-) regulation of health professions and its impact on economic growth or quality of services. The risk of ‘regulatory chill’ cannot be excluded.</b></p> <p>→ There is no evidence that health professions, which are not affected by the same competitive market forces as professions providing commercial services are, will in any way benefit from the Directive and not rather be negatively affected by a higher administrative burden leading to ‘regulatory chill’.</p> | <ul style="list-style-type: none"> <li>▪ The majority of evidence on which the proposal is based, focusses on commercial, legal, accounting and engineering professions, with very little research looking at any health professions in specific.</li> <li>▪ The Impact Assessment <a href="#">quotes</a> regulated professions’ impact on wages, job creation, mobility, skills and consumer information as key findings on which the proposal is based. In none of these categories do health professions face the same conditions as other professions. Nor were factors such as patient safety or quality of services measured.</li> <li>▪ For example, the <a href="#">analysis</a> of the impact of the product market reforms in Italy which affected the pharmacists’ profession was not able to measure the reform’s effects on quality of services or benefits to patient care.</li> </ul> |
| <p><b>Health professions are already highly mobile.</b></p> <p>→ Health professions enjoy a high degree of cross-border mobility, greatly thanks to the ‘automatic recognition’ regime of the Professional Qualifications Directive 2005/36/EC, featuring prominently among the ten</p>   | <ol style="list-style-type: none"> <li>1. <a href="#">Doctor of Medicine</a> (142280)</li> <li>2. <a href="#">Nurse</a> (133116)</li> <li>3. <a href="#">Secondary school teacher</a> (100689)</li> <li>4. <a href="#">Physiotherapist</a> (36144)</li> </ol>  |



most mobile professions. At the same time, they often see low levels of unemployment to the point of acute workforce shortages. There is therefore no systemic obstacle to either access to the profession or cross-border mobility.

5. [Dental Practitioner](#) (25928)

*DG GROW Database of regulated professions, Ranking: the most mobile professions for establishment, DG GROW,*  
<http://ec.europa.eu/growth/tools-databases/regprof/index.cfm>



## EUROPEAN COMMISSION

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### **GROUP OF COORDINATORS FOR THE RECOGNITION OF PROFESSIONAL QUALIFICATIONS**

#### **SUPPLEMENT TO TECHNICAL GUIDANCE ON THE NEW SCREENING FORM: HOW TO FILL IN THE PART ON PROPORTIONALITY IN THE REGULATED PROFESSIONS DATABASE**

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## 1. Introduction

The present document was prepared in order to initiate the discussion within the Group of Coordinators on possible ways forward in the exchange of best practices amongst Member States on the information about the proportionality assessments that are to be provided via the Screening Form (Section “Details on regulatory change and proportionality”). It therefore aims to supplement the current technical guidance on the use of the New Screening Form.<sup>1</sup>

*Disclaimer: the explanations and examples provided herein do not constitute approval or disapproval of proportionality assessments or of specific regulatory approaches of professions. This document aims to assist Member States, by way of exchange of practices, in understanding the Screening Form questions and to help in preparing proportionality analyses. If found to be useful, this document could be subject to continuous updates/revisions, depending on the needs expressed by the expert group and the outcomes of any future discussions.*

## 2. General remarks

According to Article 59(3) of the revised Professional Qualifications Directive<sup>2</sup> (PQD), Member States have to examine whether the requirements that restrict access to or the pursuit of a regulated profession comply with the principles of proportionality, and in particular:

- whether requirements are neither directly nor indirectly **discriminatory** on the basis of nationality or residence;
- whether requirements are **justified** by the overriding reasons of general interest; and
- whether they are **suitable** for securing the attainment of the pursued objectives and whether they do not go beyond what is **necessary** in order to attain these objectives.

Pursuant to Article 59(5) Member States have an ongoing obligation to provide information to the Commission on the new requirements they have introduced after 18.1.2016 (or amendments made to pre-existing requirements) together with the reasons why they consider these requirements to be proportionate, within 6 months of the adoption of the measure. Since April 2018, Member States ensure their compliance with this obligation by notification of regulatory changes and information about proportionality assessments via the Screening Form of the RegProf Database.

Owing to the heterogeneity of the professions and the specificities of their relevant markets, no general formula can be applied to these proportionality analyses. In each individual case, it is necessary to assess carefully whether a given restriction of access or conduct would lead

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<sup>1</sup> A link to the technical guidance is available in the Screening tab of the RegProf database.

<sup>2</sup> Directive 2005/36/EC on the recognition of professional qualifications (OJ L 255 30.9.2005, p. 22).

to a restriction of the fundamental freedom of establishment, free service provision and/or free movement of workers. Generally, the greater the degree of restrictiveness, the greater should be the importance of satisfying the public interest(s) pursued and the more thorough and substantiated a proportionality assessment should be.

The proportionality reasoning reported to the Commission via the RegProf Database does not need to consist of a fully-fledged proportionality study. However, the summary of such analysis in the form of replies to pre-agreed questions in the Screening Form should be clear, targeted and comprehensive enough to make it possible to appraise compliance with the principle of proportionality for that specific measure. The scope of the assessment is to be proportionate to the nature, content and impact of the provision (for instance, the creation of a new regulated profession would require a more rigorous assessment compared to a mere change of the registration body).

Regulation of professions may concern one or more of the following requirements (the following list follows the drop-down menu of the Screening Form):

#### Market entry requirements

##### Regulatory approach

Protected title – professional title is reserved by the state to the holders of specific professional qualifications.

Reserved activities – some professional activities are reserved by the state to the holders of specific professional qualifications.

Reserved activities and protected title – both a professional title and some professional activities are reserved by the state to the holders of specific professional qualifications.

The professional activities reserved to the holders of required qualifications can be **exclusive** (monopoly) or **shared** with other regulated professions (and therefore less restrictive).

##### Competency requirements

Qualification requirements (mandatory minimum education, examinations and training, professional traineeships, professional experience) to get access to the professional **activities reserved** to the holders of required qualifications or to use a professional title).

Continuous professional development – when it is mandatory for the pursuit of a regulated profession.

Language requirements – requirements for the knowledge of language(s) necessary for practising a regulated profession.

*NOTE: Both regulatory approach requirements and qualification requirements will always be present in case of a regulated profession within the meaning of PQD. This follows from the definition itself of a regulated profession in Article 3 of PQD. Please make sure that both these requirements are always indicated for the regulated professions you enter into the database together with any other requirements that apply (**please enter information/updates for ALL the relevant requirements prior to submitting the updated Screening Form to the Commission**)<sup>3</sup>.*

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#### **Other**

#### **entry requirem ents**

Compulsory registration or membership with a chamber, professional association or a state body.

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#### Quantitative restrictions:

- Limitations to the number of licenses granted.
  - Fixing a minimum or maximum number of employees, managers or representatives holding particular professional qualifications.
  - Territorial restrictions (requirements that restrict a professional's right to exercise the profession on the entire national territory. This may be the case where the licences are granted with specific geographical boundaries).
  - Age restrictions regarding access to exercise a profession.
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#### Other authorisation requirements:

- Authorisation procedures or requirements for accessing a profession ("other" in the sense going beyond other notified requirements, e.g., check of criminal records, financial standing, compliance with business premises requirements, etc.).
  - Authorisations for the exercise of specific activities within the scope of the profession (e.g., a requirement for a specific authorisation to work on electrical infrastructures part of the national grid for an engineer).
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<sup>3</sup> To report all relevant requirements via the Screening Form, please use the function "Add New Requirements" for each requirement that you introduce as many times as it is necessary to complete the form. To edit the requirements already in the form, please use the function "Edit". These steps should be completed **prior** to activating the function "Submit to Commission".

## Requirements specific to temporary or occasional provision of services (Art.7 PQD)

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### Prior declaration & documents

Mandatory prior declaration might be required when the service provider first moves into the country. It can be subject to annual renewal, require submission of specific information and be subject to a fee.

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Accompanying documents (documents required to be provided with the declaration, including requirements for translations and/or certified copies).

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## Exercise requirements

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### Requirements on specific corporate forms/incompatibilities

Corporate form requirements: specific legal form requirement(s), to the extent they are directly linked to the exercise of the regulated profession (can the professionals organise their practice under any corporate form or are there restrictions on the type of entity?)

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Restrictions related to shareholding and/or voting rights: specific requirement(s) relating to shareholding and/or voting rights in a company, to the extent they are directly linked to the exercise of the regulated profession (e.g., an obligation to have a minimum percentage of shares or votes to be held by professionals with specific qualifications)

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Prohibitions on joint exercise of professions: restriction(s) on the exercise of a regulated profession jointly or in partnership with other types of professions or activities

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Incompatibility rules: this concerns situations where the professional himself may not exercise certain activities (e.g., tourist guide cannot be a travel agent at the same time)

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|--|---|
| <b>Professional indemnity insurance requirements</b> | Mandatory insurance cover or other means of personal or collective protection with regard to professional liability.                    |
| <b>Tariff requirements</b>                           | Requirements that define level of the fees or prices charged by the professional to the service recipient.                              |
| <b>Restrictions on advertising</b>                   | Restrictions on advertising by professionals in one or more given media, as regards the content and method of commercial communication. |

The following categories of requirements **do not** necessitate a proportionality analysis under the Screening Form (so-called ‘exceptions’):

- 1) **Requirements laid down in specific EU legislation leaving no discretion to Member States on how to implement them** – Member States should specify which EU legislation lays down the requirements and explain why it does not leave any discretion as to how to implement it.
- 2) **Requirements having no restrictive effect (purely editorial and/or technical changes)** – Member States should clearly explain the contents and nature of such requirements.

Additionally, where specific requirements were notified under **the Services Directive 2006/123/EC** and where the assessment of compliance with the principle of proportionality has already been carried out as required under the PQD, Member States may choose to indicate in the Screening Form the relevant IMI reference of the notification under the Services Directive. [In addition, pending technical linkages between the two IMI modules, MSs are also requested to attach a copy of the assessment notified under the Services Directive].

*NOTE: Any use of such exceptional circumstances must be adequately justified in the respective fields of the Screening Form (!)*

### 3. Non-discrimination

As a first step in the analysis of newly introduced or amended requirements restricting regulated professions, Member States should assess if the notified measure ensures that those requirements are neither directly nor indirectly discriminatory on the basis of nationality or residence. Discrimination (direct or indirect) is found where two groups comparable in relevant ways are treated differently, or where not-comparable groups are treated the same way. Apart from overt discrimination by reason of nationality, there may be situations of covert [indirect] discrimination involving cases where the measure in

question is intrinsically liable to affect migrant professionals more than nationals (e.g., residence requirement would affect essentially migrant professionals, as this condition can be more easily satisfied by nationals than by non-nationals).<sup>4</sup>

Where the requirement is not discriminatory, Member States shall confirm so in the Screening Form.

#### 4. Public interest objectives

For any proportionality analysis, first the public interest objectives will need to be identified.

Member States may consider the following: public policy, public security or public health, preserving the financial equilibrium of the social security system; the protection of consumers, of recipients of services and of workers; the safeguarding of the proper administration of justice; ensuring the fairness of trade transactions; the combating of fraud and the prevention of tax evasion and avoidance, and the safeguarding of the effectiveness of fiscal supervision; transport safety; the protection of the environment and the urban environment; the health of animals; intellectual property; the safeguarding and conservation of the national historic and artistic heritage; social policy objectives; and cultural policy objectives. While this list is non-exhaustive, it reflects the current case-law of CJEU in the area of the freedom of establishment, free movement of workers and the freedom to provide services, which may evolve over time.

It should be noted that the terms “public policy”, “public security” and “public health” are concepts of European Union law that stem directly from Article 52 TFUE. These concepts have been consistently interpreted by the ECJ in a narrow sense, meaning that there must be *a genuine and serious threat to a fundamental interest of society* and it is for the Member State invoking these public interest objectives to demonstrate the risks involved.<sup>5</sup>

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##### **Example**

Hairdresser (**public health**): Vocational training on disinfection and health and hygiene regulations **protect customers** ... Moreover, knowledge about first aid is mandatory because of the use of tools such as knives or scissors.

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In the *example above*, while the measure is said to protect public health, the arguments brought forward are essentially linked to the prevention of damages to the recipients of hairdresser services, so to consumer protection.

It should also be pointed out that according to settled CJEU case-law, purely economic reasons, namely promoting the national economy to the detriment of the fundamental

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<sup>4</sup> Case C-237/94 *O’Flynn v Adjudication Officer* [1996] ECR I-2617.

<sup>5</sup> See *Judgment of 14 December 2006 in Case C-257/05, paragraph 25*.

freedoms, as well as purely administrative reasons, such as carrying out controls or gathering statistics, cannot constitute an overriding reason in the public interest.

## 5. Suitability (the “fit” between the measure and its objective)

To meet the requirement of proportionality, a measure should be suitable and appropriate for securing the attainment of the objective pursued.

The following issues would need to be considered:

### *Whom the measure aims to protect?*

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#### Examples

*Service recipients: consumers, patients, etc.? Professionals?*

*Third parties (is there an impact of professional activities beyond those who are paying for such a service?)?*

Clinical Dental technician: In order to secure protection of the **patients** it is necessary to make sure that ...

Crane operator: health and safety of the **worker** and **others** (fellow workers) that are in his proximity.

Dietician: making the exercise of the profession of dietician subject to examination of the required skills gives the **consumer** and the user of a service (**patients**) and the **employer** (e.g., hospitals) the necessary certainty about these skills.

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In the last *example* the regulation of dieticians is aimed at, inter alia, protecting employers in the same way as it protects consumers/recipients of services. However, no consideration is taken of the fact that employers (hospitals) are in a very different situation compared to consumers. Only the latter do not have the high level of technical knowledge needed to assess the quality of the service and the service provider. It is therefore questionable whether the measure in question is at all aimed at protecting the needs of employers. Should there be such a need to protect employers, it should be explained why employers are not in a position to assess the skills of their employees.

### *What are the risks the measure aims to minimise, or the benefits it aims to maximise, for the pursuit of the public interest objectives? How does the measure operate to achieve those objectives?*

The national measure should effectively contribute to achieving the objective pursued. The Member States should (1) clearly identify the specific risks or benefits the measure aims to minimise or maximise, (2) explain in what manner and to what extent the concrete measure achieves the specific goal(s) pursued. This is one of the most important parts of the

assessment and it requires a thorough analysis based on facts that are able to show that there are indeed relevant risks and that the measure would be able to mitigate these risks. General statements about the measure being beneficial for service quality or consumer protection are not sufficient but need to be corroborated by a meaningful analysis.

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### **Examples**

Tax adviser (consumer protection): The recipients of taxation services are business organizations, central government agencies, civil organizations. The work of tax advisors ensures transparent and correct taxation processes and practices inside the companies. The main risks of the service lie in incorrect or false taxation processes, statements, analysis, etc., which could indicate wrong economic decisions, resulting significant damages to the organizations and to the central state budget. Tax advisors are to fully satisfy the requirements as to professional competence, for instance, bearing adequate professional knowledge or taking part on compulsory education about the new and modified regulations. Well-educated tax advisors with up to date information can minimize the risks and guarantee the correct taxation services.

Architect (protection of clients): The regulation seeks to minimise the risk associated with provision of services by an unqualified person... It also seeks to maximise the quality of the services provided by architects and guarantee a standard of competence whilst ensuring protection of the rights and interests of the clients.

- The academic qualification required for practice of the profession serves to guarantee the knowledge and skills needed for said practice and ensure compliance with the standards in terms of quality and safety that a client can expect.

- Protection of the professional title guarantees to the public that the service provider satisfies the requirements for enrolment in the Association of Architects, thus fostering a relationship of trust between the client and the qualified professional.

- Ethical standards ensure working relationships between professionals and between them and society.

Physiotherapist (protection of public health): The education and training requirements for physiotherapists were introduced with the aim to protect, promote and maintain the health and safety of the public.

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In the example on tax advisers, an effort is made to identify the different types of risks involved, indicating that not only direct business clients but also the state budget could be affected. However, while a long explanation is given, the actual link between the specific measure (i.e., education requirement and reserved activities) and the risks (i.e., incorrect/false taxation processes leading to wrong economic decisions, damage to organisations, state budget) is not genuinely analysed. Indeed, it is assumed that reserving the activity of tax advice to “well-educated” tax advisors will minimise that risk. However, other dimensions of service quality, such as the availability and accessibility of the service (e.g., where the increase in educational requirements results in a fall of the supply/less of practitioners, service quality may also suffer) or price/accessibility (some consumers might prefer “lower” quality rather than very expensive high-tech tax advice). Likewise, it is not

explained how the specific measure, i.e., the specific reserved tasks and educational requirements, is tailored to the specific risk. For instance, whether the tasks performed by tax advisors in these different types of organisations is always of the same complexity and thus justifies reserving the activity of tax advice solely to highly educated professionals. Or whether it has been considered that, for instance, civil organizations typically have less complex tax statements and thus could benefit more from being able to hire less expensive professionals to prepare these (lower benefit from measure).

In the example on architects, there is no explanation about the risks that would result from the provision of services by unqualified persons. Similarly, it is neither explained what is meant by “the quality of the service” nor how the specific competency requirements ensure that quality. For instance, if the regulatory approach is limited to title protection (no exclusive reserved activities), one might argue that the skills requirements combined with the title protection allow to foster trust between the client and professionals, while leaving access to the same activities open to professionals without such protected title that could serve consumers with different preferences (i.e., less risk of reduced supply or unwanted price increase).

In the last example, the correlation between the imposed educational requirements for physiotherapists and the desired outcome (public health and safety) is not explained at all. In addition, the protection of public health is confused with the protection of the health of service recipients.

***Whether and how you assessed whether the objective is being pursued in a consistent and systematic manner?***

A measure should be considered to be suitable for securing the attainment of the objective pursued only if it genuinely reflects a concern to attain that objective in a consistent and systematic manner (without contradictions or incoherencies), for instance where similar risks related to certain activities are addressed in a comparable way.

For instance, in the DocMorris case<sup>6</sup> the Court of Justice had to examine if a national rule that precludes non-pharmacists from owning and operating a pharmacy constituted a proportionate restriction of the freedom of establishment. The Court pointed to inconsistencies in the way this rule was applied in relation to three types of pharmacies: community pharmacies, inherited pharmacies and hospital pharmacies.

The need to show consistency does not necessarily limit itself to activities within the same economic sector (e.g., where relevant, a comparison could also be made in relation to other pertinent activities or professions, such as “crafts”, “liberal professions”, public function, etc.).

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<sup>6</sup> Joined Cases C-171/07 and C 172/07, §42, DocMorris NV.

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### **Examples**

Health care services (registration with a state body): [MS] has no professional register other than that for **health care professions**. At present there are plans for adding **social welfare professionals** to the same register that contains the details of health care professionals. The register of professionals is considered to function reliably and systematically. The register makes it easier for [authority] to conduct its monitoring exercises and therefore reduces risks to patient safety and public health. It also boosts the confidence that the public has in the professionals themselves and the service system.

Real estate agent (multiple requirements): The **real estate agent's** role as intermediary can be compared with that of the **insurance intermediary**. An insurance intermediary must also be registered, covered by a liability insurance and have adequate training.

Real estate agent (reduced/removed requirements) Professional qualifications resulted in an unwanted division of the market between **real estate agents** themselves and, for example, **appraisers**. Abolishing the title of real estate agent could guarantee more equal chances on the market.

Personal services: hairdressers, beauticians, pedicurists, massagists, opticians, etc. Technical construction activities: electrician, drainage, pipe fitter...

Physiotherapist: Yes. Comparable professions are met with the same requirements.

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In the first example above, a comparison is made between healthcare and social welfare professions. However, there is no explanation on how these registration systems are comparable in terms of similar risks being addressed with regard to the two groups of professions. The statement that the register is considered to function reliably and systematically is not substantiated.

In the second example on real estate agents, the Member State could explain in more detail why the risks involved in both professions are comparable and thus warrant the same type of regulatory response.

In the examples for physiotherapists, the Member State did not at all assess or explain whether the objective is being pursued in a consistent and systematic manner.

***Have you taken into account any scientific and technological developments, which might effectively reduce the asymmetry of information between professionals and consumers?***

Markets for professional services are often characterized by an asymmetry of information between consumers and professionals as to the quality of the service. Given the complex nature of some professional services that require a high level of technical knowledge on the

side of the professional, consumers might find it difficult to judge the quality of the services provided to them.<sup>7</sup> Hence, consumers will need to be able to trust the professional. To instil such trust, regulators have tried to indirectly influence quality of the professional services by relying upon different types of access and conduct requirements.

As explained by AG Jacobs in Pavlov and Others<sup>8</sup> “[s]uch an asymmetry between seller and buyer arises *where the buyer cannot fully assess the quality of the product he receives*. In the professions, the problem is particularly acute because of the nature of their highly technical services. The consumer cannot assess the quality of those services prior to purchase by inspection (as he could for example when buying cheese), but only after consumption. Even worse, he might never fully understand whether or not the professional (e.g. doctor, architect, lawyer) provided a high quality service... The usual methods of overcoming or mitigating the negative effects of asymmetric information, or in other words of preventing a ‘race to the bottom’, can all be found in the professions. Access examinations are intended to guarantee a high initial standard of skills. Liability rules, the consequences of a good or a bad reputation, and certification schemes are incentives to exploit those skills to the full. Advertising is seen by some as a means of overcoming or mitigating asymmetry, whilst others claim that advertising exacerbates the problems.”

In addition to the quality of the actual service provided, consumers may face difficulties in assessing the level of qualification of service providers that might be essential for the delivery of services of a high quality. This asymmetry of information may prevent consumers from making informed service provider choices. To remedy the risk of potential market failures, measures like title protection clarifying the technical knowledge and competences of professionals might provide consumers with the information and reassurances they need.

However, scientific and technological developments might help to reduce this information asymmetry. For instance, the rise of the internet has greatly enhanced the amount and sources of information available to every citizen. Hence, objective quality assessments by experts or by more experienced users have become more easily available. Likewise, the possibility to exchange experiences with a large community of consumers might create more informed consumers.

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<sup>7</sup> See for instance, Case C- 94/04 Cipolla, where the Court acknowledged that “in the field of lawyers’ services, there is usually an asymmetry of information between ‘client-consumers’ and lawyers. Lawyers display a high level of technical knowledge which consumers may not have and the latter therefore find it difficult to judge the quality of the services provided to them.”

<sup>8</sup> Case C-180/98 - Pavlov and Others, Opinion of AG Jacobs, [2000] ECR Page I-06451, para. 86.

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**Examples**

Lawyer (reserved activities): [...] other alternatives for compulsory representation by lawyers in proceedings were also considered. Although it is possible, in principle, for legal experts, who are not lawyers, to perform work that is currently performed by lawyers, for example on the basis of a system of licences and accreditations, the evaluation committee does not believe that the advantages outweigh the disadvantages. Partly because of the information asymmetry between the client and legal service provider, the diversity of different service providers would not make it simpler to choose a good legal service provider. Enhancing and maintaining the quality of legal services would also become very complex. The threshold above which legal representation in civil proceedings is compulsory was recently raised to €25,000. As a result, there is actually a limited procedural monopoly for lawyers. [Sources redacted].

Real estate agent (reduced/removed requirement): Several aspects were taken into account when considering liberalization of the real estate agent profession. A protected title has little to say about actual quality. The check that measured the quality of the agent was only done once, when the agent applied for the title. Certification, by the market, on the other hand, contains a periodic check whereby continued quality can be guaranteed. Also, more requirements can be asked with a certification scheme. Because of the new features of the real estate market, mainly the decline of information asymmetry between agent and customer, the market became more capable to create quality (expertise) norms. The real estate market was already very organized by associations, allowing this market to apply self-regulation.

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In addition, digitalisation as well as scientific developments more generally have the capacity to reduce the complexity of some of the tasks traditionally performed by professionals, thereby potentially reducing the need for certain qualification requirements.

***Have you assessed the impact of the measure (for instance, on the degree of competition in the market, the quality of services, consumer choice, as well the impact on the free movement of persons and services within the Union)?***

The measure should take into account the ultimate impact of the regulation on the users of the services. While the protection of consumers and ensuring quality of professional activities could in theory be used to justify many measures (always provided the analysis is based on facts and has a sufficient depth), other considerations, such as the impact of regulation on prices, competitiveness, consumer choice or the free movement could counterbalance this.

For instance, in case of regulation by way of reserved activities subject to the possession of specific qualification requirements, Member States cannot limit their analysis to a presumption that this will automatically improve consumer protection and/or the quality of services. Also, qualification requirements while leading to the acquisition of specific skills, as

such do not necessarily ensure a high level of quality of the process or service provision or even the output. Other aspects should also be taken into account, such as whether such new regulation might reduce the number of service providers active in the market, and if such a reduction in the number of service providers could negatively affect the quality of services, including via a reduced availability of the service to less well-off consumers.

Finally, one should take account of the impact of regulation on free movement, both from the perspective of outgoing and incoming professionals/services. Member States should assess whether and what impact the measure in question would have on cross-border EU mobility.

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### **Examples**

Pharmacists (tariff requirements): In case C-148/15 *Deutsche Parkinson*, by looking at the aspect of competition, the Court found that setting of fixed prices for prescription-based (Rx) pharmaceuticals had a greater impact on pharmacies established in other Member States (foreign mail order pharmacies) than on German pharmacies. The Court could not see how this measure could be suitable for the attainment of better geographical distribution of traditional pharmacies in Germany.

Assistant nurse (qualification requirements and reserved activities): The newly created nursing profession has access to a clearly defined range of professional activities, which can be objectively separated from those of a general care nurse. Furthermore the professional titles used by these professionals are clearly distinct. For these reasons, national provisions creating an assistant nurse, qualified below the minimum requirements of Directive 2005/36/EC, would not make the market of [MS] less attractive to the incoming professionals meeting the minimum harmonised standards, nor is it likely to inhibit outbound mobility of general care nurses from [MS].

Physiotherapist (multiple requirements): We have not assessed the economic impacts of the measure, but we strongly believe there will be a great benefit for the health system economy.

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In the example for nurse assistants, the Member State has analysed possible impacts of the newly introduced nursing profession on the activities of general care nurses benefiting from the automatic recognition based on harmonised minimum requirements under PQD. However, the impacts of the measure on outbound mobility of the nursing assistants has not been analysed.

In the example for physiotherapists, the Member State did not at all assess wider impacts of the measure.

## 6. Suitability: questions specific to reserved activities

*Please explain whether and how you have assessed the connection between the scope of activities reserved to the profession and the professional qualification required? Have you assessed the connection between the complexity of the tasks and the professional qualification required (with regard to the level, nature and duration of training required)? Have you assessed the relevance of the degree of autonomy in the exercise of the profession as well as the impact of organisational and supervisory arrangements (in particular, where activities are pursued under supervision/responsibility of a duly qualified professional)?<sup>9</sup>*

The broader the scope of reserved activities, the larger the exclusive right to provide these services.

The examination of reserved activities should consider the level of the required qualification as compared to the complexity of the tasks reserved to the profession. The less complex these tasks are the less there is a justification for reserving these activities. The autonomy and level of responsibility in performing those tasks should also be taken into account (the less responsibility the professional has when performing those tasks, the less there is justification for reserving activities).

In some cases, narrowing the scope of reserved activities by sharing some activities with other professions might still suffice to achieve the desired public interest objective. If, for instance, professionals from abroad request partial access to some but not all of the reserved activities, this might be an indication of the need to examine whether the existing regulation is still proportionate.

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<sup>9</sup> See also, case C-76/90 Säger, §18, and case C-79/01, Payroll Data, §34:

"In that respect, it is appropriate to point out that it is for the national court to establish the nature of the activities of the DPCs [data processing centers]. If it concludes that the services of preparing and printing pay slips offered by Payroll involve essentially the execution of instructions and do not require any special professional qualities, the disputed provision would not seem apt to protect workers' rights".

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| <b>Examples</b><br><br><i>establish the link between the specific qualification required AND the reserved activities, their complexity, and autonomy / level of responsibility</i> | <p><u>Clinical dental technicians</u> are the members of the dental health care team specifically trained and educated in the skills and knowledge necessary to provide [dental health] services to the general public. It implies that the dental technician directly works in the oral cavity of the patient. A qualified clinical dental technician is specifically educated and trained for this purpose; he is equipped with a solid technical training as a technician, supplemented with a (usually post-technician) specific training in sciences, clinical skills and interpersonal skills. A dental technician does not give injections, does not use X-rays and does not cut [...], [but] works with appliances or constructed devices only. Furthermore, dental technicians are entitled to work independently (under full responsibility) with the patients, in particular for [activities] that justify a need for minimum qualifications. These activities are clearly distinct from those of a university-trained [dental practitioner], who performs the full range of services related to [dental] health care.</p> <p>In view of clearly defined activities limited to [...] and the right to carry out [...] activities autonomously, vocational education of [n] years duration is considered appropriate to ensure the adequate knowledge and skills.</p> <p><u>Health profession:</u> In [the] health sector, the professions that are regulated require the demonstration/mobilization of a high level [of] skills, under penalty if [the] professionals apply wrong techniques in patients with damage/injury to the patient's health.</p> |
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In the last *example*, the Member State did not at all assess the connection between activities reserved and qualifications required.

***Please also explain whether and how you have assessed the possibility of sharing the reserved activities with other professions.***

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|-----------------|--|
| <b>Examples</b> | <p>Case C-451/03 Servizi Ausiliari Dottori Commercialisti, §§39-43:</p> <p>Some of the <u>services reserved</u> to CAF [<u>tax advice centers</u>], such as delivery of a copy of the tax declaration and of the tax payment schedule, filing the tax declarations with the tax authorities and informing employers responsible for the collection of tax of the effect of the tax declaration, are essentially simple and do not require any specific professional qualifications.</p> <p>The Court found that it is obvious that the nature of those services could not justify their provision being limited solely to holders of a particular professional qualification. Such activities should therefore be open to other professionals.</p> <p><u>Real estate agent:</u> all activities exclusively reserved.</p> |
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In the last *example*, the Member State did not at all assess the possibility of sharing activities with other professions.

## 7. Necessity

***Please explain whether and how you assessed whether existing rules of specific or general nature (e.g., product safety legislation, consumer protection laws, penalties/criminal sanctions in case of illegal exercise of professional activities) are insufficient to protect the public interest objective pursued.***

Requirements should be considered necessary only where existing measures, such as product safety law or consumer protection law, cannot be regarded as being suitable or genuinely effective to achieve the aim pursued. Member States are invited to look at the existing safeguards offered through other types of ex-ante or ex-post regulation applicable to the services provided by each profession e.g. approval procedures, compliance with technical and safety standards, or inspection mechanisms.

For instance, the following example shows that service standards can be as effective as professional regulation: “Currently, the activities of hair and beauty salons are governed by the Hygiene Standard “Health and Safety Regulations for Beauty Services”, which was approved by the Minister. The mentioned Hygiene Standard gives the definition of the services (of decorative cosmetics, hair care, etc.) and sets out the requirements for the premises, tools, equipment and other inventory as well as for the provision of services. The said Hygiene Standard, however, is silent on the qualifications of the service providers as well as the limits to their competencies. [...] In 2013, the associations of beauty professionals were holding meetings with the educational institutions, who provide training for the staff in the beauty services sector, as well as the state authorities [...]. It has been concluded that new Standards for Beauty Professionals and amendments of the current Hygiene Standard are necessary in order to clearly define the limits to the competencies of the said professionals. The said national standards are in the process of development thanks to the funding from the EU Structural Funds.”

***Have you considered the possibility of using less restrictive means to achieve these objectives?***

Member States should carry out a comparison between the measure at issue and alternative, less restrictive means that would result in the same objective being attained but would impose fewer restrictions.

Examples of alternative means to regulation:

- ***Voluntary codes of conduct***, i.e. creation by professional organisations (chambers, orders, etc.) of voluntary rules and standards without legally binding nature. This is of particular relevance when assessing whether there is a need to newly create a

professions. While the specialised knowledge of professional organisations can in certain cases make them better placed to identify the best way of meeting the public interest objectives, a model of compulsory membership of professional organisations with delegated state powers to define and enforce professional rules may also carry the risk of resulting in biased regulation or might be conducive to anti-competitive and rent seeking practices.

- ***Voluntary certification schemes:*** voluntary certification systems are often used by professions that are not regulated by law. Their main objectives are to demonstrate professional competence, guarantee quality of services and inform consumers, in the absence of regulation. Article 26 of the Services Directive promotes the development of certification systems and quality labels to enable assessment of the competence of service providers and to ensure high quality of service. Some certification schemes are developed by regulatory bodies appointed by state authorities. These practices aim to improve the transparency of professional activities for the consumers and help them choose between different service providers. However, they may create practical obstacles to the access of professional activities. They could, for example, favour the development of dominant professional associations, leading to the isolation of new entrants from other countries: although access to the professional activities would be unrestricted by law, certification would become a necessity on the market; at the same time, in the absence of state regulation, the system of recognition provided for in Directive 2005/36/EC would not apply.
- ***Regulated education and training:*** training programmes, including apprenticeship periods, can be developed, under the control of the State, to prepare individuals to carry out specific professions' activities, which are non-regulated. The qualifications delivered act as quality assurance for employers and consumers when the access to the profession as such is not regulated and when there is no reserve of activities.
- ***Protection of the professional title (without reserved activities):*** In this case, a specific qualification is required to use a professional title, but the activity associated with the profession is not reserved to the holders of this title: anybody can exercise the activities, as long as they do not use the title. A protected professional title is a signal for consumers and employers that the holder meets the particular qualifications requirements, whilst leaving them free to hire professionals who do not hold the title.
- ***Regulation for special modes of pursuit*** of the profession (e.g., only for managers, for supervisors/responsible persons, shareholders, salaried staff, self-employed, for activities subject to reimbursement from social/public funds, for public/private sector, other). For instance, regulating a profession which is mainly exercised by self-employed professionals could perhaps be considered as proportionate. The situation is different if the profession is mainly exercised by professionals employed in private companies or public entities where employers have a role to play in checking the

competence of newly recruited staff and are responsible in the case of accidents or complaints.<sup>10</sup>

- **System of ex post controls** (e.g., processes, standards, safety controls, etc.).
- **Liability rules** which ensure that a provider is liable for faulty services and damages caused. Such rules depending on how they are designed are likely to produce a potentially strong incentive to display a high degree of diligence.

Where the measures are justified by consumer protection only and where the risks identified are limited to the relationship between the professional and the consumer and therefore do not negatively affect third parties, Member States should assess whether their objective could be attained by means that are less restrictive than reserving activities to professionals. For instance, where consumers can reasonably make a choice between using the services of qualified professionals or not, less restrictive means, such as protection of the professional title or enrolment on a professional register, should be used. Regulation by way of reserved activities and protected professional title could be considered only where the measures aim to prevent a risk of serious harm to public interest objectives, such as public health.

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<sup>10</sup> E.g., the engineering profession is not regulated in France where 95% of engineers are employed in a company or in public administration and recruitment is heavily based on the reputation of engineering schools (COM/2013/0676 final).

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## Examples

Urban planner (protected title): The current system is designed to **protect the title** of urban planner. It is functional. On several occasions a system of profession protection with **reserved activities** was considered. This option was rejected, because there are enough instruments that guarantee safety standards. Another option was to make architecture a **protected profession**, but the general conclusion was that this would amount to over-regulation and would therefore be inappropriate for the disciplines concerned. A system of **voluntary certification** was also considered by, amongst others, the evaluative report on the [Act]. The report concluded that replacing legal title protection with private certification – as in the case of estate agents – was not appropriate for the four architectural disciplines, for the following reasons: • the individual character of the four disciplines differed significantly from that of estate agent; • the low level of organisation in the architecture sector (30% at that time) compared with estate agents (90 %); • instead of one arrangement and one register for all four disciplines at least four certification systems and organisations would be needed, which is not transparent; • if the [Act] were scrapped, everyone would be free to call themselves an urban planner. The certification system would then become far more extensive and cost much more than the current registration system. The number of architects from the four disciplines who would participate in the certification system would be far lower than the number that now applies for registration.

Cook: No alternative mechanism was considered suitable to secure the food chain.

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In the last *example*, the Member State did not at all assess the possibility of alternative mechanisms.

***For requirements concerning qualifications, have you considered alternative possibilities to obtain the required professional qualification (e.g., other training options, or a combination of training and professional experience, etc.)?***

When the measure concerns qualification requirements, this question requires Member States to assess how flexible the system is to obtain the required credentials. The more possibilities (pathways) there are, the less restrictive the system could be considered. For example if for a given profession, it is possible to obtain the qualification by either going through a vocational secondary programme, a combination of professional experience and periods of training or the passing of a test, it would be less restrictive compared to a situation where the vocational secondary programme is the only route to obtain the qualification.

While the mere fact that there are no alternative pathways to obtain a qualification would not make the measure automatically disproportionate, the assessment should take due account of this criterion depending on the regulatory context of a given profession.

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**Examples**

Accountant: Yes, four pathways were introduced to access the profession: 1. pass entry exam+traineeship+final exam; 2. Master degree+traineeship+final exam; 3. PhD, or university professor or Member of Academy, specialisation field in economic studies, plus interview; 4. licensed accountant + final exam on certain disciplines.

Tax advisor: No, there is one pathway only (general post-secondary education of minimum 3 years and the State exam, followed by 6 months of professional practice).

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In the second *example*, the Member State did not explore any alternative training possibilities to allow access to the profession of tax advisor nor did it explain the reasons for having one pathway only.

Please note that each pathway to obtain a qualification shall be entered individually in the Screening Form (for this purpose, tick “yes” to a question “Are there other pathways to obtain qualifications?”)

## **8. Combined effect**

***Please explain whether and how you assessed the effects of the notified measure when combined with other existing requirements? Please explain how the notified measure when combined with other requirements would contribute to and whether it is necessary to achieve the same objective(s).***

According to the Court of Justice’s case-law, the national legislation should be considered as a whole taking into account the various relevant rules aimed at ensuring the attainment of the objective relied upon.

Member States should carry out a comprehensive assessment of the circumstances in which the measure is adopted and implemented and examine in particular the effect of the new or amended provisions when combined with other requirements restricting access to, or the pursuit of, the profession. The taking-up and pursuit of certain activities may be conditional on complying with several requirements. Therefore, when assessing the effect of the new or amended provisions, Member States should take into account the existing requirements, including continuous professional development, compulsory membership of a professional organisation or body, registration or authorisation schemes, quantitative restrictions, specific legal form requirements and shareholding requirements, territorial restrictions, multidisciplinary restrictions and incompatibility rules, requirements concerning insurance cover, language knowledge requirements, to the extent necessary to practise the profession, fixed minimum and/or maximum tariff requirements, and requirements on advertising.

The mere fact that their individual or combined effect should be assessed does not mean that those requirements are *prima facie* disproportionate. For example, the obligation to

undergo continuous professional development might be suitable to ensure that certain professionals keep abreast of developments in their respective areas, as long as it does not lay down discriminatory and disproportionate conditions to the detriment of new entrants. However, where the introduction of additional requirements duplicates requirements which have already been introduced by a Member State in the context of other rules or procedures, such requirements cannot be regarded as proportionate to achieve the objective pursued.

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**Examples**

Cook (qualifications and reserved activities): Due to the fact that the current regulatory framework lays down only one measure on this profession no cumulative effect can be mentioned.

Health profession (qualifications, reserved activities, registration): The requirement for the professional to sign up to the register increases transparency towards both the government as well as consumers. While the obligation to possess certain qualifications before entering the profession already ensures the required standard of skills, a register further helps to increase trust among consumers and makes it possible for government to actively control/supervise those inside the profession. Hence, the requirements in place are designed with different objectives and do not duplicate each other.

Engineer: There is no cumulative effect. Our measures are very clear and well established and are not redundant in their effect.

... we haven't reviewed the cumulative effects of the measures. The current system is working as intended. It is not considered, that it would be beneficial to change the system

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In the last *example*, the Member State did not at all assess the combined effects.

## **9. Supporting information or data**

***Please provide any relevant information you have gathered (such as qualitative and/or quantitative evidence) regarding the concrete effects of the measure.***

The reasons for regulating invoked by a Member State should be accompanied by specific evidence substantiating its arguments. Although a Member State does not necessarily have to produce a specific study or a specific form of evidence or materials establishing the proportionality of such a measure prior to its adoption, it should carry out an objective analysis, taking into account the specific circumstances of that Member State, that demonstrates that there are genuine risks for the achievement of public interest objectives.

Member States are not expected to submit such information in full via the Screening Form. However, where such supporting information or data exists, it should be clearly referred to in the screening form, and where available, with relevant links to publicly available sources.

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## Examples

Architect: As the number of architecture students and, accordingly, the number of professionals, has grown, we have witnessed corresponding growth in the turnover in the sector and improved quality of design and construction, which have been reflected in the dissemination of the architect as an added value that guarantees the quality of the final product, enhancement of the public space and protection of the historic and cultural heritage of the built environment (Sources: [redacted]).

Child supervisor: Fukkink, R. G., & Lont, A. (2007) Does training matter? Meta-analysis and review of caregiver training studies. *Early Childhood Research Quarterly*, 22 (3), 294-311. The European Quality Framework ([http://ec.europa.eu/dgs/education\\_culture/repository/education/policy/strategic-framework/archive/documents/ecec-quality-framework\\_en.pdf](http://ec.europa.eu/dgs/education_culture/repository/education/policy/strategic-framework/archive/documents/ecec-quality-framework_en.pdf)): "There is a broad consensus among researchers, practitioners and policymakers that the quality of ECEC and ultimately the outcomes for children and families depends on well educated, experienced and competent staff. The quality and relevance of staff training has a direct effect on practitioners and an indirect effect on children." p.31 This "staff" is not only the child care worker, but also the responsible or manager that runs the child care setting. The risk of a bad managed child care location is limited.

Example: There is no relevant information on the concrete effects of the measures.

Crane operator: [Due to regulation] [t]he number of accidents in [the MS] relating to the operation of cranes is, in comparison to similar countries, very low.

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In the last *example*, the Member State did not indicate any sources underlying its assessment or the relevant figures and did not analyse these alleged statistical findings as to whether they were indeed linked to the degree or type of regulation.

## 10. Conclusions

The Commission looks forward to the exchange of views of participants in the GoC meeting on 26.11.2018 concerning the present guidance document, which aims to initiate the discussion on the way forward on how to exchange best practices amongst Member States on their proportionality assessments. If need be, any of the topics of this paper can be discussed in the upcoming GoC meetings.

The participants are also invited to reflect about any additional/more specific support action that is needed in cooperation with other Member States, such as dedicated/sector/profession-specific discussions, discussion on specific requirements or assessment criteria, possible sources of evidence (e.g., how one could measure the link between regulation and quality) that need to be further explored, etc.

Contact: Alma BASOKAITE, [GROW-E5@ec.europa.eu](mailto:GROW-E5@ec.europa.eu).