



Comment on the compliance of COM (2018) 51 with the principles of subsidiarity and proportionality

(Non-official summary of the original version, drafted by the commenting region)¹

1. Commenting region / institution

Please specify the region and institution that comments.

Thüringen State Parliament, DE

2. COM - Document

Please specify the EU initiative the comment refers to by indicating its reference and its title.

*Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU
COM (2018) 51 final*

3. Type of Comment

Please specify the type of comment.

- ☒ Comment
 - ☒ on the legal basis of the EU initiative
 - ☐ on the infringement of the principle of subsidiarity
 - ☒ on the infringement of the principle of proportionality
 - ☒ on better lawmaking
- ☐ General Comment

¹ The form has been developed in cooperation with the Thuringia State Parliament.

4. Legal basis

Please specify your comment in relation to the EU competence to act regarding the initiative.

- ☒ No / wrong legal basis conferring on the EU the competence to act

5. Subsidiarity and proportionality

Please specify the reasons why the draft legislative act in question does not comply with the principles of subsidiarity and/or proportionality.

☐ **Infringement of the principle of *subsidiarity*²**

☐ **Formal infringement**

- ☐ The **justification** concerning subsidiarity included in the draft legislative act does not fulfill the requirements set in article 5 of the Protocol on the application of the principles of subsidiarity and proportionality.

☐ **Substantive infringement**

- ☐ The proposed action is **not necessary** because
- ☐ the objective/s of this action can be sufficiently achieved by the Member States, either at central, regional or local level;
 - ☐ the issue being addressed has no transnational aspects;
 - ☐ existing EU measures and/or targeted assistance provided in this framework are sufficient to achieve the intended objective/s.
- ☐ The proposed action **does not provide a clear benefit** (like economies of scale, legal clarity, homogeneity in legal approaches) compared with action at central, regional or local level.
- ☐ Other reasons or explanations (please specify):

☒ **Infringement of the principle of *proportionality*³**

- ☐ The proposed **form** of action (legal instrument) legislates to an extent which is not necessary to achieve the intended objective/s (e. g. a directive instead of a regulation would be sufficient)
- ☒ The **content** of the proposed action exceeds what is necessary to achieve the Intended objective/s (e.g. too detailed directive).
- ☒ The proposed action does **not leave sufficient room for national decision**.
- ☐ Other reasons or explanations (please specify):

² Art. 5 (3) TEU

³ Art. 5 (4) TEU

6. Better lawmaking

Please indicate the reasons why the EU initiative at stake does not respect the principle of better lawmaking.

- ☒ Local and regional aspects are not taken properly into account.
- ☐ Local and regional authorities have not been properly consulted in the process leading to the EU initiative.
- ☐ Arguments put forward in the impact assessment in support of compliance with the subsidiarity and proportionality principals are not sufficient.
- ☐ The implementation of the proposed action would entail disproportionate financial/and or administrative burdens⁴ and associated costs.
- ☐ In the case of a draft regulation: the proposal is not sufficiently detailed (essential elements may have to be provided for by delegated acts).
- ☒ Other reasons or explanations (please specify):

**The EU has no competence to regulate social security issues.
The harmonization of different national social security systems is not appropriate, because it does not allow to take regional interests and peculiarities into consideration. It is therefore necessary to leave sufficient room for national decisions. Moreover, assessments should be free from any political influence.**

7. General comment

Please specify your comment.

⁴ Administrative burdens are the costs borne by business, economic operators, citizens and public authorities in the process of complying with information obligations imposed by legislation which they would not have collected and provided in the absence of such legislation.