

Asia: VN/12980/2025

## **Luonnos hallituksen esitykseksi digipalvelulain 6 a §:n muuttamisesta (tekoäly neuvonnassa)**

### Lausunnonantajan lausunto

**Voitte kirjoittaa lausuntonne alla olevaan tekstikenttään**

Consultation Response

Consultation: Amendment to the Act on the Provision of Digital Services – AI-enabled advisory services

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Date: 16th March 2026

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Language: English

#### 1. Introduction

Clarifi Oy is a Helsinki-based regulatory strategy firm working at the intersection of European regulatory frameworks for emerging technologies, including artificial intelligence, digital health systems, and medical technologies.

Our work focuses in particular on how multiple EU regulatory frameworks interact in the governance of emerging technologies.

We welcome the opportunity to provide comments on the proposed amendment concerning the use of artificial intelligence and automated systems in advisory functions within digital public services.

The Finnish Act on the Provision of Digital Services (306/2019) establishes requirements for digital services provided by authorities, including obligations related to accessibility, transparency and user rights.

As public authorities increasingly deploy automated advisory systems, it is important that the regulatory framework evolves in a manner that maintains transparency, legal certainty and alignment with European legislation governing artificial intelligence.

## 2. General observation

AI-enabled advisory systems have significant potential to improve the accessibility and efficiency of public services.

Properly implemented systems may:

improve access to information outside normal service hours

support citizens in navigating complex administrative procedures

reduce administrative burden for both users and authorities.

However, as the capabilities of AI systems increase, advisory tools may unintentionally move beyond informational guidance into areas that may trigger additional regulatory obligations under EU law.

This is particularly relevant where automated systems begin to provide guidance that could reasonably be interpreted as:

health-related advice

risk assessments affecting individuals

recommendations influencing legally relevant decisions.

Without clear governance frameworks, authorities may unintentionally deploy systems that fall within stricter regulatory categories.

## 3. Interaction with EU regulatory frameworks

An important consideration is the interaction between national digital service legislation and EU regulatory frameworks governing artificial intelligence and sector-specific technologies.

Under the EU Artificial Intelligence Act, certain AI systems used by public authorities may fall within high-risk categories, particularly when they influence access to public services, rights or benefits.

In addition, advisory systems that provide health-related guidance may potentially intersect with the scope of the EU Medical Device Regulation, depending on their intended purpose and functionality.

Examples may include:

symptom-checking systems

triage support tools

automated health risk guidance systems.

Where such systems influence health-related decision-making, they may fall within the regulatory definition of software as a medical device (SaMD).

Ensuring coherence between national legislation governing digital services and relevant EU sectoral regulations will therefore be important in order to avoid regulatory uncertainty.

#### 4. Transparency and user awareness

Transparency toward users should remain a core principle when deploying AI-enabled advisory systems in public administration.

Users should clearly understand:

when they are interacting with an automated system

the intended purpose of the system

the limits of the information provided.

Particular care should be taken where AI systems generate responses dynamically, as users may attribute a higher degree of authority to such responses than intended.

Clear communication regarding the informational nature and limitations of automated guidance may help prevent misunderstanding and support responsible use.

#### 5. Governance and oversight

The deployment of AI-enabled advisory systems raises governance questions that extend beyond technical implementation.

Public authorities may benefit from establishing internal procedures that address:

risk assessment before deploying AI-based advisory tools

coordination between supervisory authorities where regulatory boundaries overlap

clear thresholds distinguishing informational assistance from decision-support systems.

Such governance frameworks can help ensure that innovation in public services develops in a manner consistent with both national legislation and European regulatory developments.

## 6. Recommendation: regulatory coordination and practical guidance

To support responsible innovation in AI-enabled public services, it may be beneficial to consider the following measures:

### 1. Cross-agency guidance

Practical guidance clarifying how AI advisory systems interact with EU regulatory frameworks, including the AI Act and sector-specific legislation where relevant.

### 2. Early regulatory consultation

Encouraging authorities developing AI advisory tools to consult supervisory bodies early in the development process.

### 3. Pilot environments or regulatory sandboxes

Controlled testing environments could allow public authorities to evaluate AI advisory tools prior to broader deployment.

These measures may help reduce regulatory uncertainty while supporting innovation in public services.

## 7. Conclusion

AI-enabled advisory systems have the potential to significantly improve accessibility and efficiency in public administration.

To achieve this safely and effectively, it will be important to ensure:

transparency for users

alignment with EU regulatory frameworks

appropriate governance structures within public authorities.

Clarifi welcomes continued discussion on this topic and would be pleased to contribute further technical perspectives if additional stakeholder discussions or workshops are organised.

## About the author

Clarifi Oy is a Helsinki-based regulatory strategy firm specialising in European regulatory frameworks for emerging technologies, including artificial intelligence, digital health technologies, and medical devices.

The author, Stephen O'Rourke, works on regulatory strategy and compliance for companies developing AI-enabled health technologies and other regulated innovations across European regulatory frameworks, including the EU Artificial Intelligence Act and the EU Medical Device Regulation.

Clarifi's work focuses on helping organisations navigate regulatory systems while supporting responsible innovation in emerging technologies.

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