28 September 2023

Ursula von der Leyen, MD
President, European Union (EU)
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Charles Michel, JD
President, European Council (EC)
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Submitted electronically to:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13446-European-standardisation-evaluation/F3436780_en

Re: European Commission’s Call for Evidence Regarding Regulation 1025/2012

Dear Drs. Von der Leyen and Michel:

Health Level Seven (HL7) International welcomes the opportunity to submit feedback on the European Commission’s Call for Evidence relating to the evaluation of Regulation 1025/2012, which outlines the EU’s standardisation policy. HL7 is the global authority on healthcare interoperability, an American National Standards Institute (ANSI)-accredited Standards Development Organization (SDO) and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries. Particularly of note for this submission, HL7 has a regional office and Foundation in Europe as well as 23 Affiliate members on that continent. The eHealth Network --the European Union body responsible for drafting specific eHealth guidelines--has also noted that HL7 Fast Healthcare Interoperability Resource (FHIR) should be considered for future primary use cases of the EHDS (i.e. lab results, medical images and reports and hospital discharge reports). More information can be found at:

http://www.hl7.eu/about.html

http://www.hl7.eu/board.html

http://www.hl7.eu/affiliates.html

HL7 agrees with the Call for Evidence statement that “since Regulation 1025/2012 on European standardisation was adopted in October 2012, the standardisation environment has changed significantly.” As a world-leading SDO whose standards and tools are deployed across the globe, HL7 represents and embodies this change. HL7 is contributing to notable transformation in the healthcare sector and beyond, aiding implementers across the information and communications technology (ICT) spectrum that work towards better data integration and interoperability. We are on the front lines of standardisation change and are in support of achieving key goals highlighted in Regulation 1025/2012 and related documents such as:

- Enabling standards to be quickly and efficiently available;
- Assuring interoperability between devices, applications, data repositories, services and networks so that Europe can reap the full benefits of ICT;
- Using standards to address key societal challenges; and
- Making cooperation between standardisation bodies more transparent.

It is from this vantage point, that HL7 offers its expertise to you as you continue to evaluate potential changes and adjustments to Regulation 1025/2012. Please call on HL7 for feedback as appropriate. HL7 International is a proven and valuable convening arena for both Regional Affiliates and interested government and non-governmental organizations.

HL7 also emphasizes support of key feedback themes in the letter submitted by ANSI regarding current review and evaluation of Regulation 1025/2012. Examples of this include:

- **The Global Economy and Standards** - The EU’s approach to Regulation 1025/2012 may lack the necessary flexibility to address urgent needs in rapidly evolving technology areas and has the potential to lead to fragmentation or duplication between: (a) European standards and specifications and (b) global standards and specifications. This should be examined in order to anticipate and address current and future standardization needs in today’s global economy.

- **Standards Definition** - Regulation 1025/2012 considers only the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and International Telecommunications Union (ITU) to be “international standardization bodies”. This definition should be expanded to include international standardization organizations that develop their deliverables according to the World Trade Organization (WTO) principles as referenced in the Regulation. The flexibility provided under Regulation 1025/2012 for ICT technical standards/specifications should be extended to all standards and specifications. The broadly and deeply deployed HL7 FHIR is an excellent illustration of this. Such an approach could facilitate provision of cross-border services, encourage competition, and promote interoperability and innovation.

- **Improved Coordination** - Better coordination is needed between the European Standardization System (ESS) and organizations contributing to the development of all sets of global standards. This will address today’s complex value chains and tackling shared global challenges in effective and timely ways.

- **WTO Principles and Clarification** - Regulation 1025/2012 points to the need for European standardization activities to: (a) adhere to the WTO principles that seek to ensure that such efforts are inclusive, open, transparent, consensus-based, etc. and (b) coordinate with international standardization bodies (including but not limited to ISO, IEC and the ITU). We are interested in further understanding how these requirements will demonstrably be fulfilled.
In closing, HL7 appreciates your on-going collaborative process and applauds review of whether the current Regulation 1025/2012 can still sufficiently respond to the new opportunities and challenges of globalization, ensure the public’s safety, and support the green and digital transition. Our HL7 leadership, Policy Advisory Committee, International Council, HL7 Europe Foundation and wide spectrum of HL7 Work Groups can help the EU and EC in this on-going task. Our organization is dedicated to advancing inclusive, equitable and integrated standards solutions in Europe and across the global digital health landscape.

Should you have any questions about our comments or want to engage further, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. Catherine Chronaki—Secretary General of the HL7 Europe Foundation—is also a valuable resource on this matter and can be reached at chronaki@HL7europe.org. We look forward to continuing this discussion.

Sincerely,

Charles Jaffe, MD, PhD
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Health Level Seven International

Andrew Truscott
Board of Directors, Chair
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