



On 10 December 2015, the CPME Executive Committee adopted the ' CPME Response to the Public consultation on Standards in the Digital Single Market: setting priorities and ensuring delivery' (CPME 2015/115 FINAL)

CPME Response to the Public consultation on Standards in the Digital Single Market: setting priorities and ensuring delivery

The Standing Committee of European Doctors (CPME)¹ represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

The CPME Responses to the Public consultation on Standards in the Digital Single Market: setting priorities and ensuring delivery are highlighted in **light green** in the following pages.

¹ CPME is registered in the Transparency Register with the ID number 9276943405-41.

Standards in the Digital Single Market: setting priorities and ensuring delivery

Fields marked with * are mandatory.

General information on respondents

* Do you wish your contribution to be published?

Please indicate clearly if you do not wish your contribution to be published.

YES

NO

Submissions that are sent anonymously will neither be published nor taken into account.

The Commission may contact you in case a clarification regarding your submission is needed. If you do not wish to be contacted, please state this clearly in your reply.

I wish to be contacted:

YES

NO

* I'm responding as:

An individual in my personal capacity

The representative of an organisation/company/institution

* What is your nationality?

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Italy

Ireland

Latvia

Lithuania

Luxembourg

Malta

Netherlands

Poland

Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom
Other

*What is your place of residence?

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Italy
Ireland
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom
Other

*What is your name?

Constance

*What is your surname?

Colin

*Please enter your email address:

Constance.colin@cpme.eu

Please enter your telephone number:

+32 2732 72 02

* Please enter the name of your institution/organisation/business:

Standing Committee of European Doctors (CPME)

* Is your organisation registered in the Transparency Register of the European Commission and the European Parliament?

Yes

No

* Please indicate your organisation's registration number in the Transparency Register.

Please register in the [Transparency Register](#) before answering this questionnaire. If your organisation/institution responds without being registered, the Commission will consider its input as that of an individual and as such, will publish it separately.

9276943405-41.

*

Please enter the address of your organisation:

15 rue Guimard

1040 Bruxelles

*

My institution/organisation/business operates in:

EU

Austria

Belgium

Bulgaria

Czech Republic

Croatia

Cyprus

Denmark

Estonia

France

Finland

Germany

Greece

Hungary

Italy

Ireland

Latvia

Lithuania

Luxembourg

Malta

Netherlands

Poland

Portugal

Romania

Spain

Slovenia

Slovakia

Sweden

United Kingdom
Other

* What is the primary place of establishment of the entity you represent?

Brussels

* Please indicate your main field of business activity and the field of activity related to the consultation's topic (if not identical to the overall business activity).

Healthcare / eHealth

* Please select the description that applies to your organisation.

Public authority

European Standardisation Organisation (CEN, CENELEC, ETSI)

International Standardisation Organisation (ISO, IEC, ITU)

Other Standard Setting Organisation

Research Center

Industrial Association, Forum & Consortium

Other Stakeholders Association (e.g. Users, Consumers...)

Enterprise (not SME)

SME

Other

* Indicate the size of your company.

In accordance with the European Commission Recommendation 2003/361.

See also [Online help](#)

Medium sized enterprise (independent companies that have less than 250 employees, and either whose turnover is $\leq 50M\text{€}$, or balance sheet $\leq 43M\text{€}$)

Small enterprise (independent companies with less than 50 employees, and either turnover or balance sheet $\leq 10M\text{€}$)

Micro enterprise (independent companies with less than 10 employees, and either turnover or balance sheet $\leq 2M\text{€}$)

* Is your organisation active in ICT standardisation?

Yes

No

Questions

II.1 Questions on general framework and problem statement

It is of particular interest to understand if the standards currently under development effectively match interoperability and successfully creating a Digital Single Market. In addition, it is especially interesting to identify those actions in standards development that could act as a solution for wider industry and public needs, not limited to the specific technologies that have been standardized.

Please indicate whether you agree to the following statements and explain your answer briefly.

Q1.1 - Do you share the Commission's analysis in Part 2 of the [analysis document](#)?

Part 2 states:

“1.2 Analysis

Standards are developed by a number of different actors as part of a voluntary process, which is consensus-oriented. Regulation (EU) No 1025/2012 on European standardisation³ recognises CEN, CENELEC and ETSI as European standardisation organisations (ESOs) and ITU, ISO and IEC as formal international standardisation bodies. For the purpose of this consultation, standard setting organisations comprise these formal standardisation organisations as well as international fora and consortia developing ICT technical specifications in accordance with the WTO founding principles.

The European standardisation is organised by and for the stakeholders concerned based on national representation (CEN and CENELEC) or direct participation (ETSI). International standard organisations, such as ITU, ISO and IEC are also playing an important role and European experts are also actively participating in them. At the same time, in particular in the digital sphere, ICT technical specifications are increasingly developed by fora and international consortia (e.g., W3C, IEEE, IETF, OMG, OASIS, ECMA, OMA, Open Group, etc.).

It will be important to promote timely standard-setting that reflects European interests as much as possible. As is to be expected, standard-setting organisations have limited resources to organise their activities, so they will need to make critical choices and organise standard-setting work accordingly. At the same time, there are important socio-economic policy and public interest objectives, notably the effective functioning of the Digital Single Market that EU and its Member States are keen to promote. Therefore, in order to organise standardisation work effectively and to ensure appropriate sequencing and timely availability of standards priorities should be set up.

It is with these objectives in mind that the European Commission in its Digital Single Market Strategy adopted on 6 May 2015 proposed "to launch an integrated standardisation plan to identify and define key priorities for standardisation with a focus on the technologies and domains that are deemed to be critical to the Digital Single Market (...)".

YES

PARTLY

NO

NO OPINION

*

Please explain:

CPME agrees that key priorities for standardisation should be identified. In healthcare, the definition of technical standards for ICT is essential. CPME very much supports efforts to promote the interoperability of eHealth applications across Europe, the aim however being not only technical interoperability, but also the maintenance of the highest possible standards of usability and, most crucially, data protection and confidentiality.

CPME however strongly opposes the increasing number of initiatives aiming to create technical standards for healthcare services, both at national and European level. Standardisation institutes have put forward proposals to create standards affecting professional practice. These operate outside the framework of expertise which professional bodies offer with regard to technical qualifications, ethical requirements, professional regulations, treatment procedures and quality assurance. At worst such so-called standards conflict with existing guidelines and recommendations for practice.

In the healthcare sector, the mandate of standardisation institutes should therefore be limited solely to technical specifications for ICT and other products/facilities; their mandate should not extend to healthcare services provided by healthcare professionals to patients.

Q1.2 - ICT is assuming a greater role in sectors of the economy which were not previously significant users of ICT. How do you see *the role of ICT standards* for the economy, in particular beyond the ICT sector?

Very Important

Important

Modest importance

Not important

No opinion

*

Your comment, indicating a specific sector:

Sector: Healthcare / eHealth

Technical standardisation is essential to ensure interoperability of eHealth across Europe, in order to ensure swift and safe usability of the devices.

As stated in the previous question, technical standardisation should be limited in healthcare to ICT, products and facilities. It should in no way extend to healthcare services.

Q1.3 - Do you agree that setting priorities for ICT standards at EU level, accompanied by clear time-tables, could help standard-setting organisations in better organising their work and support the Digital Single Market?

YES

PARTLY

NO

NO OPINION

*

Please explain why: See response to Q1.2.

Q1.4. - What other steps should be considered to ensure that any such prioritisation would enjoy broad support of key stakeholders?

Beyond the development of standards for eHealth, it is important to ensure a comprehensive participation of stakeholders in shaping eHealth policies. The swift deployment of eHealth within the EU crucially depends on its acceptance by users, ie. healthcare professionals and patients, and requires their involvement in the development of these tools.

Q1.5 - What would be the most effective instrument at EU level to ensure that any such prioritisation is taken up by relevant standard-setting organisations? (please select and rank up to 3 instruments)

	1	2	3
A Commission Communication			x
A Commission Recommendation		x	
Standardization requests issued to EU standard-setting organisations and included in the Annual Union Work Programme for European standardisation			
Regulation	x		
Priorities stated in the Rolling Plan for ICT Standardisation			
No opinion			
None of them			

Q1.6 - What would be the impact of a priority ICT standards plan defined at the level of the EU on Europe's effort *to pursue leadership in global standard-setting*?

POSITIVE
NEUTRAL
NEGATIVE
NO OPINION

Q1.7 - What would be the impact of a priority ICT standards plan defined at the level of the EU on the ability of European companies *to capture new global market opportunities*?

POSITIVE
NEUTRAL
NEGATIVE
NO OPINION

Q1.8 - Besides establishing a priority ICT standards plan, what other measures could the Commission (or other EU institutions) take to ensure that standardisation plays its role in achieving a Digital Single Market?

Beyond the definition of ICT standards for eHealth, one should always keep in mind that eHealth should be considered as a tool and not as an aim in itself. eHealth solutions/services should always be developed with the understanding that they must first come as a support to healthcare professionals and to patients; any other use of eHealth solutions, like the support to healthcare system management, are secondary, and must take our introductory remarks into account – we reject any standardisation of medical procedures elaborated outside the framework of expertise which professional bodies offer.

Q1.9 - How should standard-setting organisations best respond to the increasing speed of technological development and the integration of technologies in business processes across all industrial sectors?

A - Regarding the *adaptation of existing standards to new developments*:

No opinion

B - Regarding the *introduction of new standards for new technologies/products*:

No opinion

Q1.10 - How do you see the involvement of European ICT Standardization experts in international standardisation organisations (ITU, ISO, IEC) and global standard setting organizations (i.e. IEEE, IETF, OASIS, W3C, ECMA international)?

A - The *SCOPE (or LEVEL?) of involvement*:

- Is appropriate
- Should be increased
- Should be decreased

No opinion

Please explain:

B - The *QUALITY of involvement*:

- Is appropriate
- Should be improved

No opinion

Please explain:

II.2 Questions on priority domains for standardisation in the Digital Single Market

In this section, the Commission invites survey participants to express opinions and ideas on setting priorities for ICT standardisation.

The Commission has identified 10 domains set out below, as well as a set of sub-domains within each domain. Please note that domains and subdomains are interrelated and that overlaps are possible and desirable in particular with respect to synergies between different sectors. Some domains are horizontal and may benefit a large number of sectorial applications; some other domains are more sectorial and were identified as areas where ICT standardisation would bring important benefits. First check whether the list of domains is complete and relevant. If the list is considered incomplete, please complement it with additional domains that you consider priority.

Q2.1 - Please identify and rank the domains (up to 5) and subsequently subdomains (up to 3 per domain) within each domain that you consider a priority. If specific domains or subdomains are missing please add them.

at most 5 answered row(s)

	1	2	3	4	5
Domain 1: 5G communications					

Domain 2: Cloud computing					
Domain 3: Cybersecurity					
Domain 4: Data driven services and applications					
Domain 5: Digitisation of European Industry					
Domain 6: eHealth and aging	X				
Domain 7: Intelligent Transport Systems (ITS)					
Domain 8: Internet of Things					
Domain 9: Smart Cities					
Domain 10: Smart and Efficient Energy Use					
Others					

Domain 6: eHealth and aging
at most 3 answered row(s)

	1	2	3
Drug identifiers for medical prescriptions			
ICT infrastructure for the implementation and delivery of services for independent living in age-friendly buildings			
Interoperability profiles for independent living (Interoperability profiles describe specific solutions to interoperability in a specific use case scenario. A profile documents how standards will be used in order to achieve interoperability. Profiles ensure implementers and users that they are talking about the same solution without having to restate all the technical details that establish actual interoperability.)			
Interoperability profiles for mHealth apps			
Quality criteria for health and wellness apps		x	
Security and Safety of mHealth apps			x
Semantic interoperability of Electronic Health Records	x		
Telemedicine			

projects to contribute to standardisation									
Community Building									
Support creation of public-private partnerships - PPP									
Increase strategic coordination of ICT standardisation at EU level.									
Ensure consistent application of existing standards									
Accelerate the identification of ICT technical specifications most commonly used for their reference in public procurement									
Other									
No opinion	x								

Q2.5 - Please indicate any other standardisation initiatives which would help achieving the Digital Single Market in the **Domain 6: eHealth and aging** and the subdomains which you have selected, and who in the standardisation landscape would be best placed to lead on these initiatives:

None

Q2.6 - Would your organisation be prepared to invest resources in standard-setting to achieve the priority standards within the proposed time-frames?

Please answer this question only if you are responding as the representative of an organisation/company/institution.

YES

YES, provided some conditions are met

NO

No opinion

*

Please explain your choice and specify conditions:

* yes, under the condition that all costs incurred are entirely covered

II.3 Other Comments

Other comments:

None