CPME/AD/EC/15092016/078_Final/EN

On 15 September 2016, the CPME Executive Committee adopted the 'CPME response to the public consultation on the safety of apps and other non-embedded software' (CPME 2016/078 FINAL)

CPME response to the public consultation on the safety of apps and other non-embedded software

CPME answers appear in **blue font**.

1. Introduction

This consultation concerns software and apps which are neither embedded, nor contained in a tangible medium at the time of their placement in the market, their supply to consumers or when they are otherwise made available to consumers (non-embedded software). Examples include health and well-being apps that can be used on a mobile device, digital models for 3D printing or apps controlling other devices (such as electronic appliances).

The purpose of the consultation is to gather input from various stakeholder groups, in particular consumers, businesses and authorities, on their experience related to the safety of apps and other non-embedded software. The questions aim at obtaining a better understanding of the possible risks and problems that non-embedded software may pose and how these problems could be dealt with.

The views gathered will help to define potential next steps and future policies at the EU level including, if appropriate, possible revisions of existing horizontal and/or sector-specific EU legislation.

If apps are giving access to a service, this consultation addresses only the safety aspects in the functioning of the app, and not the underlying service itself (e.g. transport or accommodation). For the purpose of this consultation, only apps and non-embedded software that are downloadable on a device such as a personal computer, tablet or smartphone or accessible on a remote location (cloud) would be covered.

For the purpose of this consultation "safety" and "safe use" should be understood as freedom from unacceptable danger, risk or harm, including security-vulnerabilities ("cyber-security") and cover physical, economic as well as non-material damage.

This consultation will only look into the safety of apps and other non-embedded software which is not already addressed and foreseen by sector-specific legislation such as the Medical Devices Directives, the Machinery Directive or the Radio Equipment Directive which include provisions on safety ensuring that equipment within their scope, if compliant, is safe.

2. General information on respondents

3. Consultation:

3.1 For individuals or representatives of a public authority / organisation / business.

In your view:

* 1. What type of apps or other non-embedded software pose safety risks? Please give examples.

The number of health and well-being applications (apps) is steadily growing. However, many of them can be associated with safety risks for citizens/patients relying on them, in the absence of an appropriate assessment and monitoring framework.

Health and wellbeing apps are commonly used to monitor various factors that impact health, including weight, blood pressure, cholesterol, or even evaluate skin lesions.

* 2. What risks can apps or other non-embedded software pose?

X Economic damage
X Physical damage to individuals
Physical damage to property
X Non-material damage (pain and suffering)
Other:

*Please explain: **Lack of performance, inaccuracy and ineffectiveness can often cause unnecessary anxiety among citizens/patients (blood pressure, cholesterol measure..) or, on the contrary, lead to underestimate a problem (detection of skin lesions). In addition, cyber-security risks should not be underestimated.**

Please give your opinion on the following options:

	No risk	Low risk	High risk	Very high risk

*Economic damage			X	
*Physical damage to individuals			X	
*Physical damage to property	X			
*Non-material damage (pain and suffering)			X	
*Other				

Please explain:

* 3. In which sectors are apps or non-embedded software most affected by safety problems?
Agriculture
Electronic Communications / Telecommunications
X Health
Home automation/ Domotics
Energy
Financial
Transport
Other
Please specify:

3.2 For representatives of a public authority / organisation / business. In your view:

*4. In your professional experience have you already identified unsafe apps or other non-embedded software or have consumers approached you because they encountered problems with unsafe apps or other non-embedded software?
X Yes
No

Please specify:

Doctors often face patients using ineffective/inaccurate apps on a daily basis to monitor physiological factors. It can be associated with anxiety expressed by the patient as a result of unexpected/alarming results provided by the app.

Very problematic too is of course under-diagnoses, with the risks it represents for illnesses which should be treated rapidly. One example is the apps used to detect skin lesions. If these apps seem to fall under the MD definition, the performance of these apps has been put in question in various studies. For example, the most accurate apps in one study missed 18 of the 60 lesions diagnosed as melanoma[1].

4.1 If yes: What did you do to solve these problems?

*5. Are existing EU or national safety rules and market surveillance mechanisms sufficient to monitor and withdraw, where necessary, unsafe apps or non-embedded software from the market?
Yes
X No

Please explain: **Healthcare professionals are not aware of any specific system to declare problems encountered with applications, apart from the vigilance system related to medical devices.**

*6. Have you been held accountable for damage caused to consumers because of unsafe apps or other non-embedded software?
Yes, as manufacturer of the device the software runs on or controls
Yes, as an app or software manufacturer/developer
Yes, as an intermediary/distributor (e.g. app store)
X Yes, other
No
Doctors' liability when using mHealth services should be clarified. Doctors and patients would expect that the medical service they provide and receive through mHealth is legally viable.

6.1 If yes: What did you do?

*7. Do you think that existing horizontal and sector-specific EU legislation (e.g. General Product Safety Directive, Market Surveillance Regulation, Medical Device Directive, Radio Equipment Directive) taken together sufficiently cover the safety of all types of apps or other non-embedded software available on the market?
Yes

[1] http://archderm.jamanetwork.com/article.aspx?articleid=1557488&resultClick=3

X No

Please explain: **The delimitation between apps having a sole wellbeing/lifestyle purpose and apps having a medical purpose is often blurred. For instance, blood pressure and diet data used in wellbeing/lifestyle apps may very well be medically relevant.**

Consequently, health and wellbeing apps, which do not fall under the definition of medical devices, should undergo independent assessment before entering the market, especially to verify the performance of these applications with regard to their claim (i.e. in terms of accuracy and effectiveness).

*8. Have you considered opening up an Application Programming Interface (API) of a device you manufactured or a service you provide to app and software developers to link their app to your device/service and use its functionalities? If so, have you taken into consideration safety aspects?

Not applicable

*9. Has the legal framework on safety influenced your decision on whether to invest in developing apps or software?

Not applicable

*10. In the EU Member State where you operate, are there specific rules on safety requirements for apps or other non-embedded software?

Not applicable

*Please select the country where you operate:

Not applicable