DIGITALEUROPE

DIGITALEUROPE Response to European Commission Questionnaire on Second Draft of EU mHealth Assessment Guidelines

Brussels, 11 August 2016

Question 1 - Please tell us how we can get in touch with you if we need to discuss your comments further

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Question 2 - Please tell us how you heard about this consultation

Name and Date of event attended where consultation was invited – DIGITALEUROPE is a member of the expert Working Group and heard of the consultation directly from the Working Group facilitators

Please reference email your received inviting you to comment – N/A

Other – N/A

Question 3 - Section 1: Introduction; Background and Regulatory Landscape

I agree with the text of the draft – Yes and No

Please make any comments on or suggested corrections to the text below or at the end if you need more space

We welcome the inclusion of these sections as a way to set the framework so that readers understand why we are undertaking this exercise. This is the first step in clarifying the scope of the guidelines. However, we questions why the issue of 'risk' and 'safety' is brought up on page 1 as this does not accurately reflect the outcomes of the stakeholder meetings nor the reason for the creation of the guidelines. The scope of the exercise from the beginning was to address the quality of data for linking apps to EHRs. This exercise should therefore not cover 'safety'. Furthermore, while an overview/roadmap may be useful for readers during the drafting phase, we do not believe it is necessary for the final guidelines and as such should be removed prior to final publication.

When it comes to the overview of the regulatory landscape, we believe that this section is extremely important so that readers (and Working Group Members) understand that we do not need to 're-invent the wheel' on many issues. It also shows that any expansion of scope risks contradicting clear regulatory frameworks that already exist or are set to be implemented in the near future. However, we wish to express caution on the 3rd paragraph on page 10 (*Section 1.2.4.1 Interfacing with medical devices legislation*). Here the drafters begin to build up the "grey

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zone". The role of this guidance is NOT to define where the borders lie for a so-called "grey zone" as that would have implications on safety. If the Working Group decides that safety is of importance, then it should be for the European Commission and stated actors to define a process to effectively draw the line and address the points. Safety is the competence of the European Commission experts. It is not for an ad-hoc group (despite its best intentions) to declare what is safe and what is not. Moreover, the European Commission recently launched a consultation looking at the safety of non-embedded software. The consultation covers the Product Safety Directive, which is the right place to have a discussion on safety.

Lastly, we wish to note that those standards mentioned on page 12 (*Section 1.2.5 Existing standards*) are principally those that relate directly to medical devices, which fall outside of the scope of the guidelines. This should be specified more clearly. Furthermore, to give a complete overview of standards, it might be worthwhile to includes those related to app security and privacy. Standards in this field exist and a reference could be useful to readers. Examples of standards to be mentioned are ISO27034 for application security and ISO29151 & ISO29134 for privacy.

Question 4 - Section 2: Purpose

I agree with the text of the draft – Yes and No

Please make any comments on or suggested corrections to the text below or at the end if you need more space

As above, we believe that including a section on 'purpose' is important. We particularly welcome the first paragraph of this section as this reflects the main purpose of the guidelines. However, we object to the inclusion of paragraph 5 which states "*better use of better apps for better healthcare*". While improving adoption is a laudable goal, that is not the objective of this exercise. We need to make sure that these guidelines do not seek to advocate for the use of certain apps over others. The potential increased use of mobile apps should only be treated as an indirect positive effect of the application of the guidelines, but not a direct objective.

We also have concerns surrounding the language in paragraph 6. This is where the scope begins to extend and the mentioning of additional criteria emerges. Once again, while this is laudable, this is NOT the purpose of these guidelines and falls outside of the raison d'etre for why the group was established. This language must be narrowed as there is a risk that these 'additional criteria' would compete with other standards, other legislation, other projects, etc. This will create confusion and uncertainty.

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Question 5 - Scope of the guidelines

Feedback on the first draft reveals 2 different perspectives on scope:

1. The scope should be limited to considering only validity and reliability.

2. It is essential to consider a number of related criteria (9 are identified in this version of the draft guidelines).

What do you think?

I agree with a more limited scope (only validity and reliability). Please give reasons for your view – Yes. This is the reason for the establishment of the Working Group. It reflects the concerns raised in the responses to the Green Paper on mHealth Consultation and represents the core mandate behind the Commission's call for expression when creating the group. Any expansion of this would require a new and extended working mandate from the Commission.

I agree that it is also essential to consider a broader range of related criteria (as in the second draft) – No. We disagree STRONGLY with this. Not enough information/proof has been provided as to why we need to proceed with a broader range of criteria. The additional 9 criteria should to all apps, which begs the question as to why we are looking at them only in the context of mHealth apps.

Please amplify or provide any other comments – As noted above, the additional criteria should in theory apply to all apps, which begs the question as to why they are being looked at in the context of lifestyle and wellbeing apps only? There is competition between apps and app stores to ensure that these criteria are met. If they are not met, then the apps will not be used. Market activities have also seen changes to app store policies showing that they respect these criteria. To make this exercise useful, we need to look at things that are of real relevance to mHealth apps. This requires a narrowing down of scope and focus to the issues which are particular to mHealth apps only. Expanding the criteria outside of the core problem we are trying to address dilutes this exercise.

It is important to remember that DIGITALEUROPE, while only 1 member of the Working Group, represents 62 companies and 37 national trade associations. Our members, both large and small, note that many of these criteria contradict clear and existing criteria set by OS manufactures and recognised by Member State Governments (and market practices). This will lead to confusion and uncertainty and has the risk of impacting the business operations of companies.

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Question 6 - Section 4 of the guideline text identifies the main target groups expected to benefit from the guidelines: Citizens, mHealth Developers, App aggregators, Healthcare professionals and the healthcare system. It lists their perspectives on the shortcomings of the current situation and also their needs from the guidelines.

Please comment by target group

Current shortcomings and needs of citizens are correctly described. If not please comment – We do not believe citizens should be the target of this exercise. It is hard to believe that citizens will consult these guidelines prior to downloading or using and app. If the group thinks citizens should be a target, then a separate document (e.g. easy to reach brochure) needs to be developed to present in an easy way the criteria for choosing a good mHealth app. However, this needs to be the job or another Expert Group.

Current shortcomings and needs of mHealth developers are correctly described. If not please comment – We do believe that the mHealth app developers are the right target for the guidelines. However, the incredibly long list of criteria which contradicts many of the criteria set out in OS manufactures guidelines plus the various legislative frameworks represents the existing shortcomings in this draft.

Current shortcomings and needs of app aggregators are correctly described. If not please comment – We do not believe that app aggregators should be the target of this exercise.

Current shortcomings and needs of healthcare professionals are correctly described. If not please comment – We do not believe that healthcare professionals should be the target of this exercise. While we recognise the difficulty faced by healthcare professionals when asked by patients if the should/should not use an app, it is unreasonable to expect healthcare professionals to go through this criteria to evaluate an app. The solving of this problem should be done by national health authorities to aggregate a list of recommended apps that meet the criteria and then have this list be shared with/accessible to healthcare professionals.

Current shortcomings and needs of the healthcare system are correctly described. If not please comment – We do not believe that the healthcare system should be the target of this exercise.

Please make any other comments on targeting - are we missing any important stakeholders? Are some important needs from the guidelines being overlooked? Is it possible for the guidelines to meet all the needs of the different stakeholders? – Along with mHealth app developers, we believe that public authorities should be one of the targets for these guidelines. We wish to stress that it is NOT possible for these guidelines to meet the needs of the different stakeholders. To target all of the above target groupings would require various iterations and versions of the guidelines. While we understand that many members of the Working Group have a desire to make sure that the guidelines address their target group, it is simply not feasible. If you narrow down the scope and purpose you narrow down the target groups and the exercise becomes easier.

Question 7 - Section 5: Format and Adoption

I agree with the text of the draft – Yes and No

Please make any comments on or suggested corrections to the text below or at the end if you need more space
We agree that the guidelines should be simply to read, but if all the target groups are trying to be met, it will be impossible to create a 'simple to read' document. As stated above, if you narrow down the scope and purpose you can narrow down the target group and then the format/adoption exercise becomes easier. Right now we do not believe the different communication strategies for various audiences are feasible. We also wish to note that it would be good to emphasise the 'voluntary' nature of these guidelines within this section (and in the introduction).

When it comes to a decision tree, we believe this only works for a narrow target audience. We would like to point back to the simplicity of the mHealth Privacy Code of Conduct as an example. The aim was an easy guide for app developers on how to make apps more privacy friendly. This included a clear and succinct check-list for them. If we had tried to take that document and addressed other target groups you would have a messy and unclear document.

When it comes to the certification/labelling, we believe that if certification or labelling were to be brought up to a European level (or have mutual recognition in Member States), it could be an area to be explored. However, the requirement cannot fall onto app aggregators. They have current 50,000 apps coming into their stores per week. They do not have the expertise nor the resources to take part in certification. This is once again why we believe national authorities must be one of the target groups of this exercise.

Question 8 - On the format of the guidelines

The European Commission's Working Group is considering

- Practical support or guidance.
- Terminology (clarity on use of terms).
- Legal (clarity).
- Organisational or procedural approach.
- Criteria (to be used in assessing app).

Using the same target groups mentioned at Q6 above, please state which aspect will be most important.

For citizens, the most important aspect is (choose from Practical support or guidance, Terminology, Legal, Organisational or procedural approach, Criteria. Explain why and how this could best be delivered. – We do not believe citizens should be the target of this exercise. It is hard to believe that citizens will consult these guidelines prior to downloading or using and app.

For mHealth developers, the most important aspect is (choose from Practical support or guidance, Terminology, Legal, Organisational or procedural approach, Criteria). Explain why and how this could best be delivered.– For mHealth app developers the focus should be on practical support and guidance. We do not believe the clarity, terminology, and particularly organisational (out of scope!) aspects are important.

For app aggregators, the most important aspect is (choose from Practical support or guidance, Terminology, Legal, Organisational or procedural approach, Criteria). Explain why and how this could best be delivered. – We do not believe that app aggregators should be the target of this exercise.

For healthcare professionals the most important aspect is (choose from Practical support or guidance, Terminology, Legal, Organisational or procedural approach, Criteria). Explain why and how this could best be delivered. – We do not believe that healthcare professionals should be the target of this exercise.

For the health system, the most important aspect is (choose from Practical support or guidance, Terminology, Legal, Organisational or procedural approach, Criteria). Explain why and how this could best be delivered. – We do not believe that the healthcare system should be the target of this exercise.

Please make any other comment on the form and purpose the guidelines here or at the end. – Once again we wish to note that the guidance should be targeted at public authorities. As stated above, the entire question depends on who the target group is. However, in our view, we believe it should focus on practical support and guidance.

Question 9 - Section 6: Guidelines

I agree with the text of the draft – No

Please make any comments on or suggested corrections to the text below or at the end if you need more space We strongly disagree with this section. As previously noted we do not agree with the inclusion of the 9 criteria. They are not specific to mHealth apps and many of they have nothing to do with assessing the validity, reliability, and integrity of data that is produced by lifestyle and wellbeing apps. The scope in this section needs to be drastically reduced. We refer you to our previous consultation response where we outline why we do not think certain criteria are necessary in this exercise.

We also continue to have serious reservations regarding *Section 6.3 – Risk assessment*. As noted in question 3, this group does not have the legitimacy and mandate to draw up where the borders lie for a so-called "grey zone". Defining risk should remain the role of the European Commission and the established procedures. It not for this ad-hoc group to draw up risk definitions. We wish to draw an example with the current discussions around the GDPR. This Regulation is built on the foundation of a 'risk-based approach'. However, the definition of risk is being left to the experts within the European Data Protection Authorities (together with industry expert stakeholders). It is not being left to an ad-hoc group. As such, we call for the deletion of this section of the guidelines.

Question 10 - Feed-back on the first draft of the guidelines indicates that we need to go into more depth on the approach to Risk Assessment, Assessment Scrutiny and Scoring. We would welcome your practical suggestions on how these aspects could be improved

My suggestions for Risk Assessment are - to delete the section

My suggestions for app scrutiny are – N/A

My suggestions for scoring are (if you do not agree with scoring, please explain) – N/A

Other (please specify) - The intention of the guidelines is to focus on validity and reliability. The questions should focus on what measure are taken to make sure that the app gives good and reliable data. Introducing risk into the equation will create confusion when considering current (and future) MEDDEV guidelines, Consumer Protection legislation and the current consultation on safety of non-embedded software. As stated before, it is the job of the European Commission through its defined processes to address this issue, not for this ad-hoc group.

Question 11 - Appendices

8.1. Health Evaluation and Standardisation Bodies existing in EU

8.2. List of terms

8.3. Assessment questionnaire

8.4. Usability

8.5. Definition of interoperability

8.6. Case Studies

Please make any comments on 8.1. Health Evaluation and Standardisation Bodies existing in EU. If you are aware of a body, you think should be mentioned - please reference it and explain why it should be included We do not understand the need and added value of this section.

Please make any comments on 8.2. List of terms - This list of terms must be cross-referenced with legislation existing today that defines many of these categories. There are too many inconsistencies.

Please make any comments 8.3. Assessment questionnaire. Bear in mind, we are still working on the questions, and especially how to make them less subjective and more objective. Please reference the specific question you are commenting on, and propose more objective wording if you feel able to do so (with justification for this) These

questions need to be drastically reduced. Many of these question have absolutely nothing to do with assessing whether an app produces credible, valid and reliable data. Furthermore, many questions contradict existing OS guidelines and will lead to confusion. This goes once again back to the scope issue that must be narrowed.

Please make any comments on 8.4. Usability - We do not understand the need and added value of this section

Please make any comments on 8.5. Definition of interoperability – This section is not needed unless there is a plan to introduce the details of specific standards for interoperability. We find this section randomly placed and of little added value.

Please highlight any case studies (showing how similar guidelines have been adopted elsewhere and showcasing their impact). The Working Group is expecting to include case studies from Catalunia, Andalucia and the Netherlands, but more would be welcome. A maximum of one page of text is expected per case study – Any case studies should only include the section that address assess the reliability and validity of data. Other aspects of case studies are not relevant for this exercise and lead to confusion.

Question 12 - Please provide any further comments you may have. Thanks for taking the survey and for your valued feed-back, which will help us further refine the guidelines

As previously mentioned, it is important to remember that that DIGITALEUROPE, while only 1 member of the Working Group, represents 62 companies and 37 national trade associations. Our members employ 7.5 million people across the EU and generate €1.56 trillion. This impact must be taken into account and properly weighed when the responses to this questionnaire are analysed.

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ABOUT DIGITALEUROPE

DIGITALEUROPE represents the digital technology industry in Europe. Our members include some of the world's largest IT, telecoms and consumer electronics companies and national associations from every part of Europe. DIGITALEUROPE wants European businesses and citizens to benefit fully from digital technologies and for Europe to grow, attract and sustain the world's best digital technology companies.

DIGITALEUROPE ensures industry participation in the development and implementation of EU policies. DIGITALEUROPE's members include 62 corporate members and 37 national trade associations from across Europe. Our website provides further information on our recent news and activities: http://www.digitaleurope.org

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