TRANS-ATLANTIC BUSINESS COUNCIL

TABC Response to the European Commission Public Consultation:

GREEN PAPER on mobile Health ("mHealth")

July 2, 2014

- **Which specific security safeguards in mHealth solutions could help to prevent unnecessary and unauthorised processing of health data in an mHealth context?**

  - The creation of a taxonomy of risk while shifting regulation from data collection to data use. More specifically, a new model should include a taxonomy of presumptions concerning common data uses, based on risks and benefits associated with the use of data, to determine the appropriate level of notice and consent requirements. We could imagine a paradigm premised on three categories:
    1. uses that are broadly acceptable as low-risk (where notice and consent are not required),
    2. uses that are high-risk (that are prohibited absent explicit notice and consent),
    3. uses that are subject to individual "sentiment" (meaning that they may be acceptable to some, but reasonably objected to by others – where making a blanket rule about consent requirements may be inappropriate without a more detailed risk analysis, and where some level of choice is likely appropriate).
  - To encourage consumer confidence and public institution adoption of mHealth data, there should be standards to prevent cloud suppliers to use it for the purposes of marketing and advertising without express consent. Such consent should not be a condition of receiving the service. ISO standard 27018 provides clear guidance to procurement authorities.
  - At present, all health data is treated in the same way despite the fact that the use and analysis of it can be either very beneficial or very harmful depending on what data is used and how it is used. It is important that the positive benefits are allowed while also establishing systems to protect data that could harm individuals.

- **How could app developers best implement the principles of "data minimisation" and of "data protection by design, and "data protection by default" in mHealth apps?**

  - The Draft General Data Protection Regulation (GDPR) by the European Commission proposes an industry-wide "privacy by design" (PbD) obligation. PbD is an important element of increasing privacy through increased corporate responsibility and new technical solutions. Industry should work to ensure that privacy is engineered into products and online services at the outset of development, that all products and services are reviewed to identify privacy issues at an early stage, and that consideration of privacy and data security is present throughout the product lifecycle.
  - One strong element of the GDPR on PbD is that rather than dictate in prescriptive terms how PbD is to be implemented, the Regulation instead dictates the outcome that enterprises must be achieve – leaving technology providers free to innovate so long as their innovations protect privacy. We would recommend instead that, as part of PbD, the Regulation encourage innovators to assess the full universe of potential privacy risks and make appropriate decisions about privacy designs and settings.

- **What measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU whilst complying with legal and ethical requirements?**

    - Big data and machine learning are becoming the primary innovation paradigm. Big data refers to things one can do at a large scale that cannot be done at a smaller one, to extract new insights or create new forms of value, opening the door to new forms of understanding, in ways that change markets, science, environments challenges, organizations, the relationship between citizens and governments and more.
    - The flow and usage, and the resulting benefit of big data in the context of mobile health will depend on the same regulatory adaptation as other big data solutions. For big data to be used, we must adapt our regulatory system.
    - For example, one paradigm that should be evolved so that the value of big data can be unlocked is the shift the focus from the collection of data to how data is used.
    - Evolving how we use consent is necessary in the big data world. Context of data processing must be taken into consideration so that we do not over burden users with numerous opt-in requirements

- **Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?**

    - The GDPR introduces various measures to protect users. That said, many of these safety measures need adapting so that they are relevant and meaningful in the digital age. As stated in the question above, safety mechanisms like consent need to be evolved so that they are more meaningful and relevant in the digital age.

- **Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts; if yes, why and how?**

    - The EU Governments in collaboration with industry should adopt the strongest protection and enforcement of privacy while also taking into account the digital and big data contexts. What is needed is an adaptation of the enforcement and regulation through which the framework will be strengthened as a whole. The regulation at present does not take into account technology created after its passage and therefore, in many ways does not regulate effectively. A newer, stronger regulation must be enacted so that new technologies are allowed to flourish while personal data is protected.

- **What good practices exist to better inform end-users about the quality and safety of mHealth solutions (e.g. certification schemes)?**

    - TABC welcomes initiatives such as voluntary mHealth app libraries and directories that can help citizens and healthcare professionals alike navigate the numerous, disparate apps available on the market. Moreover, some organisations are developing app marketplaces to allow a subset of the mHealth apps to be organised and made available to citizens and healthcare professionals, thereby removing some of the uncertainty and friction associated with the huge number of apps available.

- **Which policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?**

    - We encourage before foreseeing any form of new policy action that the European Commission consider the existing legal frameworks that are in place or under review.

There is a risk of policy hindering the expected innovation from the APP economy as governments are looking to draw the line between medical apps and lifestyle apps, for example, which is an ongoing discussion in the context of the revision of the medical devices Directives.

- Another issue might be the difference between Member States as regards the implementation of this legal framework. As we are talking here about Directives, which have to be transposed into national law, there might be more or less strict approaches depending on the Member State. Another issue is the ability to enforce these rules and make controls at national level – do we need more legislation or do we need the current framework to be better enforced?
- We encourage the ISO 27018 standard to be considered into the public procurement process for any use of cloud mHealth solutions. This will better drive adoption and usage if such safeguards against commercial data mining of personal data for marketing purposes is in place.

Legal framework: at the same time as the Green Paper, the Commission published a staff working document which describes the current legal framework applying to lifestyle and wellbeing applications:

- Medical Devices Directives: currently being revised but only applying to medical applications, not to wellbeing and lifestyle applications.
- General Products Safety Directive and the Directive on liability for defective products: as they are meant to apply to manufactured goods, are they applicable to applications that are not covered by the medical devices Directives?
- Data Protection Directive and ePrivacy Directive: providing the requirements for collecting and processing health data. In addition, Article 29 Working Party "Opinion 02/2013 on apps on smart devices" clarifies the liability of each actor in the in the development and distribution of apps.
- Consumer Rights Directive: while medical apps are excluded from its scope as healthcare products, lifestyle and wellbeing apps are subject to the provisions applying to distance selling.
- Directive on Unfair Commercial Practices: protect consumers from misleading advertising.
- eCommerce Directive: provisions applying to app stores, on which information to provide to consumers prior to purchase.

- **How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?**

  - The above response also applies to this question. There is also Member State level provisions as well as standards from standard bodies.

- **Do you have evidence on the uptake of mHealth solutions within EU's healthcare systems?**

  - As correctly stated in the Green Paper, mHealth uptake still remains limited in Europe. Although technology exists today that can enable service providers and manufacturers to deploy reliable and interoperable connected devices through smart wireless communication technologies and Cloud infrastructure, there is still a lack of simple business models supporting the massive adoption of mHealth services and applications. Solutions deployed so far have been tailored and developed for specific regional or local authorities, each having different requirements, for specific use cases and situations and for the remote monitoring of specific patient pathologies and treatments. This has led to the current state of numerous pilots but no mass-market adoption of mHealth due to the lack of interoperability and economies of scale.

- There are some examples such as:

  - ✓ **European Medicines Verification System (EMVS)**: this system will manage the data of more than 10 billion pharmaceutical packs in the 27 countries of the European Union per year. Each individual package will carry a unique serial number in the form of 2D data matrix code. This code will then be verified at the end of the sales channel - at the delivery point such as a public pharmacy - whether it is exactly the number the pharmaceutical manufacturer had applied on this medicine.
  - ✓ A research team at the **University of Helsinki (FIN)** has utilized, in the treatment of breast cancer, the huge computing capacity of the cloud computing service to identify genes that can predict the progress of the disease. A computing task that usually requires some 15 years can now be completed in less than five days.
  - ✓ The **Bambino Gesù Pediatric Hospital (IT)** uses cloud computing to improve patient care and reduce costs. The hospital has a better collaboration which helps to improve patient care. They can set up collaboration sites and share patient charts and lab results. Doctors can receive patients' email messages at home or on the smartphone.
  - ✓ The Norwegian regional health authority Helse Vest can easily view hospital data and cuts patient wait time by over 67 percent with cloud solution.
  - ✓ In Netherlands, traveling clinicians such as doctors and nurses use the cloud to schedule, locate services, analyse and produce tools.

- **What good practices exist in the organisation of healthcare to maximise the use of mHealth for higher quality care (e.g. clinical guidelines for use of mHealth)?**

  - Like eHealth, mHealth describes a broad set of technologies that can support a variety of health-related services along the continuum of care, from mobile access to EHRs to telehealth and telecare. For this reason, good mHealth practices will tend to be good practices in each respective service that utilises wireless technologies. For instance, the TeleSCoPE project has developed a code of practice providing a quality benchmark for healthcare professionals and patients using telehealth services.
  - Other good practices relate to the adoption of strategies to guide the effective use of mHealth apps, such as the 'innovation centres' or 'ecosystem models' that are being implemented in the US. Similarly to app marketplaces, these models provide a sandbox in which third-party applications can be tested and vetted to ensure they work effectively in care workflows.

- **Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?**

  - Much has been said about the lack of large-scale evidence from randomised control trials on the positive impact of services such as telehealth – which largely rely on mobile technologies – on cutting healthcare costs. The much-reported cost-effectiveness studying the context of the UK Whole Systems Demonstrator found that the cost of adding telehealth was on average 15% higher than delivering usual car. We believe these findings have suffered from fundamental flaws in the design of the trials, mostly due to the short time frame and loan ensuing lack of organisational change.
  - By contrast, consistent evidence tells us that eHealth/mHealth solutions have an overwhelmingly positive quality impact on healthcare delivery processes in that they result in fewer emergency admissions, hospitalisations and bed days per intervention as well as reduced mortality, sometimes dramatically and beyond expectations. However, due to

'siloed budgeting' the full value of these net gains is not always evident to single actors in the healthcare chain as they only tend to manifest themselves over time, and thanks to scale economies the cost of new technologies is felt immediately by each actor making investment decisions in the short term. Moreover, benefits are distributed unevenly between healthcare providers, who bear most of the investment risk to build and maintain eHealth/mHealth systems, and citizens who reap most of the benefits with little or no investment.

- While we encourage public authorities to continue to study the impact of eHealth/mHealth on reducing healthcare expenditure, we believe these calculations – which mostly, if not solely, stress pure cost avoidance over the larger net benefits for society – do not show the full benefits of innovative mHealth solutions and are among the reasons causing suboptimal investments.

- **What policy action could be appropriate at EU, as well as at national, level to support equal access and accessibility to healthcare via mHealth?**

  - We welcome the Commission's efforts to stimulate the adoption of innovative eHealth/mHealth technologies and services in the Member States. We believe that the new Horizon 2020 programme goes in the right direction in trying to learn from past experience and design projects that can go beyond the current patchwork of piece-meal pilots that have failed to create interoperable and scalable products. We encourage the Commission to be even bolder to make sure European funds, including cohesion policy funds, can be used to deliver interoperable mHealth services and applications that can create large-scale access to innovative technologies for Europe's healthcare systems and citizens.
  - TABC also supports the Commission's objective, in its Connected Continent proposal, to leverage electronic communications networks and services to restore competitiveness, drive innovation and create smart, sustainable and inclusive growth. Mobile networks will play an increasingly important role in achieving these objectives as consumers shift to mobile computing platforms such as smartphones and tablets and the Internet of Things becomes a reality, creating an explosion in mobile data demand. This is particularly relevant for sectors with special societal value such as healthcare, which will not only need additional capacity – e.g. to collect a growing array of vital signs – but must also rely on high-quality, robust, resilient and secure connectivity to deliver value-added services while protecting citizens' health data.
  - Given the limitations on spectrum available for licensed mobile broadband we believe that a more rapid adoption of dynamic spectrum sharing technologies and increase in the spectrum capacity available for licence-exempt access will spur the innovation and investment needed to deliver the required connectivity – enhancing coverage and capacity. To gain the full benefits of the single market, a harmonised and coordinated approach to radio spectrum authorisation in the EU is needed, through appropriate RSPG, CEPT and ETSI activities.

- **What, if anything, do you think should be done, in addition to the proposed actions of the eHealth Action Plan 2012-2020, in order to increase interoperability of mHealth solutions?**

  - TABC believes that the actions contained in the eHealth Action Plan to foster the adoption of EU-wide standards remain valid, and indeed are even more critical, to increase the adoption of interoperable mHealth products and services where information can be

pushed and pulled seamlessly and securely between systems thanks to end-to-end, plug-and-play connectivity.

- We note that today established standards are already available and that specifications and profiles provided by organisations such as IHE and Continua can significantly expedite the testing, certification and implementation of innovative applications both inside and outside the hospital. However, these standards and profiles have been inconsistently adopted in the Member States – including in public procurement, which we believe should be one essential impact factor. We encourage the Commission to further raise awareness, and stimulate the adoption, of readily available, global standards and guidelines.

- **Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records? And if yes by whom and how?**

  - TABC believes that the interoperability of EHRs with information collected via mHealth services – particularly on high-priority health conditions through the appropriate use of remote monitoring technologies – will be essential to improve the quality, safety and efficiency of care while seeking to improve citizens' inclusion and engagement. We believe that this 'holistic' approach to interoperability will enable healthcare systems to more easily share EHRs across providers and citizens while benefiting from the interconnected value of health IT using apps and wearable technology. In particular, we believe that the release of open or semi-open APIs will allow developers to collaborate with healthcare systems on apps that, while protecting citizens' health information, have huge potential to deliver more personalised care by harnessing device-generated data in conjunction with EHRs.
  - There are several standards in use today that are driving mHealth mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, and much more.

    - ✓ **ASTM Continuity of Care Record (CCR) standard**: the (CCR) is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient. To ensure interchangeability of electronic CCRs, this specification specifies XML coding that is required when the CCR is created in a structured electronic format. Conditions of security and privacy for a CCR instance must be established in a way that allows only properly authenticated and authorized access to the CCR document instance or its elements. The CCR consists of three core components: the CCR Header, the CCR Body, and the CCR Footer.
    - ✓ **The Continuity of Care Document (CCD) specification**: the CCD combines the benefits of ASTMs Continuity of Care Record (CCR) and the HL7 Clinical Document Architecture (CDA) specifications. The CCD specification contains U.S. specific requirements; its use is therefore limited to the U.S. The U.S. Healthcare Information Technology Standards Panel has selected the CCD as one of its standards.
    - ✓ HL7 FHIR : Fast Health Interoperable Resources is a next generation standards framework created by HL7. FHIR combines the best features of HL7's Version 2, Version 3 and CDA® product lines while leveraging the latest web standards and applying a tight focus on 'implementability'. FHIR solutions are built from a set of modular components called "Resources". These resources can easily be assembled

into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts.

- ✓ IHE PCC : IHE Patient Care Coordination (PCC) domain was established in July 2005 to deal with integration issues that cross providers, patient problems or time. It deals with general clinical care aspects such as document exchange, order processing, and coordination with other specialty domains. PCC also addresses workflows that are common to multiple specialty areas and the integration needs of specialty areas that do not have a separate domain within IHE.
- ✓ **ISO/IEEE 11073 Personal Health Data (PHD)**: group of standards addressing the interoperability of personal health devices (PHDs) such as weighing scales, blood pressure monitors, blood glucose monitors and the like. The standards draw upon earlier IEEE11073 standards work, but differ from this earlier work due to an emphasis on devices for personal use (rather than hospital use) and a simpler communications model. Continua Health Alliance products make use of the ISO/IEEE 11073 Personal Health Data (PHD) Standards.

- **Which mHealth services are reimbursed in the EU Member States you operate in and to what extent?**

  - First reimbursed mHealth app in Germany: Caterna Vision Therapy is an app aimed at treating amblyopia, a common eye disease linked to strabismus, in children. The app has been certified as a therapeutic medical product in conformity with the Medical Devices Directive. It can only be prescribed by an ophthalmologist and as of 1 April 2014, it is reimbursed by one of the German national health insurance (Barmer Gek). This is a step in the right direction and we encourage more applications to have similar reimbursement across the EU.

- **What good practice do you know of that supports refund of mHealth services (e.g. payer- reimbursement model, fee-for-a service model, other)? Please give evidence.**

  - TABC believes that cross-industry research – for instance, into banking and insurance transactions – can provide insight into how healthcare payers and providers will use mHealth applications to create both revenue opportunities and cost savings. What is unique about mHealth with respect to both the clinical and financial areas of healthcare is that it affords opportunities to provide new business models as well as methods of assessing costs in this sector. Healthcare systems, including both public and private players, will therefore be positioned to increase mobile transactions, transition many of those transactions from traditionally higher-cost channels and include and engage more citizens. As the healthcare industry makes additional mobile transactions possible, the potential returns on investment for healthcare systems will increase as consumers shift to the faster, more convenient and less expensive mobile channel to make payments and access care in personalised ways.

- **What recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription of mHealth solutions?**

  - A research project has studied the incorporation into clinical care of mHealth-generated patient data and documented the professional liability concerns voiced by healthcare professionals during the study and the steps they took to manage them. Most concerns involved healthcare professionals' fear that they could not keep up with the vast amounts of patient-generated data and could therefore potentially be unable to appropriately

respond to important clinical issues that may arise from such data. The project highlighted the following strategies for healthcare professionals:

- ✓ Work with patients
- ✓ Monitor incoming data and triage as necessary
- ✓ Put in place medical emergency protocols
- ✓ Use appropriate judgment in deciding when patient-generated health data

- **Could you provide specific topics for EU level research & innovation and deployment priorities for mHealth?**

  - TABC believes that research and innovation has a key role to play in rethinking what a healthcare service should be and how it should be delivered in a user-centric approach, before considering technology. As seen in previous comments, we believe that most of the barriers to the large scale deployment of mHealth solutions stems from organisational rather than technical issues, ranging from an inconsistent adoption of existing standards and specifications to a lack of integration between mHealth services into daily operation.

- **How do you think satellite applications based on EU navigation systems (EGNOS and Galileo) can help the deployment of innovative mHealth solutions?**

  - TABC believes accurate, real-time location technologies will play an important role in creating new and more user-centric healthcare services, improving efficiency and safety and streamlining care delivery both in and outside the hospital. To give one very simple example in the app domain, an asthma inhaler with a sensor that uploads information to a smartphone app with every dispensed puff could provide alerts to air-quality issues in the area, based on the user's current location. These innovative services can already rely on multiple data sources such as GPS, cell tower location, Wi-Fi and Bluetooth Smart to deliver increased accuracy, including indoors. We believe EGNOS and Galileo will provide a useful additional layer, in this context, once they are both fully operational.

- **Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?**

  - TABC believes the Transatlantic eHealth/health IT Cooperation Roadmap can give Europe a useful incentive to advance on the path to achieving the necessary level of interoperability not just for the basic patient summary across the Atlantic but also as a basis for full-blown interoperable EHRs across the EU, so as to enable citizens' full secure access to their medical information and associated services on mobile devices.

- **Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to boost mHealth deployment?**

  - TABC believes that incentives for healthcare providers to implement interoperable EHR systems, particularly when these incentives are linked to services available to the population on mobile platforms and apps, can be an important tool to stimulate mHealth uptake and the inclusion of mobile technology into reimbursement mechanisms. The meaningful use requirements under the Medicare and Medicaid EHR Incentive Programs in order to receive financial incentives for the 'meaningful use' of certified EHR technology could act as a model in this respect.

- **Is it a problem for web entrepreneurs to access the mHealth market? If yes, what challenges do they face? How can these be tackled and by whom?**

    - To help get their products to the public, start-ups in the mHealth space have to navigate a tangled web of challenges, including not just funding but regulations (e.g. compliance with the medical devices and data protection frameworks) and complex technical issues such as interoperability, particularly for those entrepreneurs who develop more advanced applications that need to work within established healthcare settings, where the enforcement of existing interoperability standards is often inconsistent. This is arguably the most serious obstacle for small mHealth entrepreneurs to enter the healthcare market and grow their business. The EU-wide adoption of already available global standards and specifications will be key in creating better market entry conditions in this respect.

- **If needed, how could the Commission stimulate industry and entrepreneurs involvement in mHealth, e.g. through initiatives such as "Startup Europe" or the European Innovation Partnership on Active and Healthy Ageing**?

    - We support the European Commission initiatives such as Startup Europe and Tech All Stars.
    - We encourage the European Commission to engage regional governments to drive the increase of public private partnership where industry and regional governments have the right incentives to create APP development centers open to students, professional software developers, IT professionals, entrepreneurs, and academic researchers. Each provide content and services designed to accelerate technology advances and stimulate local software/APP economies through skills and professional training, industry partnerships and innovation.