Abstract — A long standing challenge for regulators has been how to incorporate new technologies into the current regulatory framework. This is especially applicable to telemedicine and e-health systems. This paper presents the regulatory framework and key issues concerning telemedicine and e-health systems development and proposes potential solutions.

Keywords: telemedicine; e-health; regulatory issues

I. INTRODUCTION

Telemedicine is defined as “the provision of healthcare services at a distance” through use of Information and Communication Technologies (ICT) [1]. It involves transmission of medical and personal data for the diagnosis, treatment, management and monitoring, and follow-up of patients. This innovative way of care can improve patients’ quality of life by giving them the exact care needed due to constant monitoring and efficient diagnosis. Telemedicine has been developing rapidly and regulators need to come up to speed. Regulation of ICT-based technologies is currently not clear and should be assessed more precisely. It is of high importance to involve both regulators and manufacturers to establish a clear, tailored framework. Moreover the regulatory structure should reflect the level of risk represented by the device.

II. TELE HEALTH / TELEMEDICINE

Telemedicine is increasingly playing a vital role in health care systems. Telemedicine offers benefits not only to patients, but also to healthcare systems and society by offering better management of health resources which result in improved cost-effectiveness/performance ratio. As the population ages and is living gradually more with chronic diseases, telemedicine could be a solution for providing medical support while optimizing the cost for “at home hospitalization” and healthcare resources. Indeed, it is estimated that health care professionals spend 30% to 50% of their time on administrative tasks rather than on patient care [2]. Although nowadays the use of telemedicine is limited due to a highly fragmented market, it is expected to experience a growth rate of over 55% by 2014-2015 [2]. Moreover, 41% of patients in the United States declare they would like to use portable monitoring equipment to send data automatically to their doctors [2]. This represents a golden opportunity for healthcare, telecoms, and consumer electronic companies as well as for software developers [2].

However, telemedicine is facing some challenges. First, industry has to look out for technological issues: more available bandwidth, network congestion, efficient storage and management of data generated. Additionally, industry has to look into providing a friendly and easy-to-use device, adapted to the user (the patient or health professional). Furthermore, reliability of the system is essential to avoid serious health consequences, up to life-threatening situations. Industry also has to manage cost issues (operational, telecommunications, healthcare professional training) and the lack of consensual reimbursement of telemedicine. These cost issues could be a restraint to the growth of telemedicine market. Lastly, telemedicine involves legal and practical issues regarding privacy and standards of practice.

Current organisation in various regions

The European Commission published in April 2011 a report on “the public consultation on the European innovation partnership on active and healthy ageing” [3] highlighting the growing need for innovative methods of care. Among future and existing initiatives, public authorities, private individuals, industry and academics promote the use of telemedicine for a healthier ageing population. However, e-health is mainly regulated by national laws in Europe; it is therefore indispensable to create a harmonized framework to ensure interoperability of telemedicine across Europe. Major projects are ongoing in the United Kingdom (Picture Archiving and Communication Systems (PACS) 8th generation), the Netherlands (Portavita patient logbook), Denmark (“Digitalization of Health Sector”) and Germany (Gematik health cards).

The United States is an extremely appealing market for industry developers given the history of deals made in this area and the knowledge in this field [2]. In the US, rural communities are making investments to facilitate the delivery of telemedicine but the slow rate of devices approved by the Food and Drug Administration (FDA) is limiting the expansion of this new technology. The US has significantly incorporated telemedicine on a national basis but faces State to State issues regarding reimbursement and legality [4].

In Japan, telemedicine may be valuable for various population sizes and densities [5]. Teleradiology and home-care telemedicine represent the biggest part of e-health projects developed in the past years. After a good start, the growth of telemedicine in Japan stagnated because of reimbursement issues and technical problems such as lack of
equipment and network infrastructure. In addition, according to Japanese law, it is forbidden for a doctor to treat a patient or to establish a diagnosis without a direct contact with the patient. This is a major hurdle to telemedicine development when physicians must be in the presence of a patient to practice formal medical care [6].

In India, federal and charitable institutions contribute to the development of telemedicine programs [7]. The government has offered incentives for telemedicine such as reduced import tariffs on infrastructure equipment. In India, 70% of the population lives in rural areas and a majority of rural hospitals have inadequate infrastructure [8]. Telemedicine could be part of the solution to provide quality health care services to people living in these remote locations.

III. E-HEALTH PRODUCTS AND REGULATORY FRAMEWORK

E-Health products used for a medical purpose may fall under the definition of a medicinal product (MP) or medical device (MD). Both are highly regulated products, with specific requirements described in National laws. These requirements may differ slightly from one country to another. In Europe, the regulation has been harmonized and is described in European directives, then transposed into National laws in each European country. Other countries such as US, Japan have national regulations, more or less close to the European regulatory framework. This can generate potential issues or challenges for developers when considering worldwide development and registration.

A. Medical devices

There is no universal definition of a medical device. As an example, Table I presents the European and FDA definitions of these devices [9, 10, 11]. The definitions in other countries are very similar.

The conformity of the products to the specific National laws and the pre-market approval by Regulatory Authorities will allow the devices to be marketed in a concerned country or continent.

The classification of these devices is mainly based on the risk to the patient—the higher the risk in terms of safety and effectiveness/performance, the more the requirements for compliance are stringent. Depending on the country regulations, these requirements may be related, in particular, to the clinical evaluation validating the performances of the device, the description of the manufacturing process and the risk analysis. In addition, the manufacturer may have to develop a quality management system and a specific vigilance system for post market surveillance.

Specific requirements may be defined for self-testing devices and associated software, assuming that these devices perform appropriately for their intended purpose taking into account the skills and the means available for the users and the impact from variation that can be anticipated in user’s technique and environment. Furthermore, the information and instructions provided by the manufacturer should be easily understood and applied by the user.

### Table I – US and EU Medical Device Definitions

<table>
<thead>
<tr>
<th>European Definition</th>
<th>FDA Definition (US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device: “medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception.</td>
<td>Medical Device: “An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.</td>
</tr>
</tbody>
</table>

B. Evolution of the regulation for medical device software

1) In the United States

Given major advances in engineering and science, software is increasingly becoming an important component in many medical devices. In many cases, software can be considered a medical device by itself. In the US, software is classified according to a risk based system, like other products that are classified as medical devices. This risk classification approach is based on the risk to the patient if the software were to fail. Classification varies from Class I (least risk) to Class III (highest risk) [12]. Class I exempt devices are required to comply with general controls and do not require a premarket notification (titled 510(k)) to be submitted to the FDA. There are some Class I and II devices which are not exempt, thereby requiring a 510(k) submission. Some class II devices are also required to comply with special control documents. For class III devices, a premarket application (PMA) will be required unless the device is a preamendment device (on the market prior to 1976 or substantially equivalent to such a device). Recently the FDA has seemed to loosen the regulations for certain software products, allowing them to be reclassified from Class III to a lower class. This new ruling applies to Medical Device Data Systems (MDDS) which are systems that provide electronic transfer, storage, exchange, retrieval, display and conversion of medical device data. When a device is indicated to be used by a healthcare professional and does not perform irreversible data compression it is exempt from premarket notification. Otherwise, if it is prescribed by a healthcare professional but for use by a lay user, performed irreversible
Another example of software considered as a medical device is related to personal therapy management system for diabetics. This therapy management software helps patients suffering from diabetes to control their blood glucose level. The data collected by the continuous glucose monitoring device and blood glucose meter are uploaded to a web-based program. The software provides a detailed report allowing the patient or the doctor to compare changes in glycaemia based on daily activities. Charts and graphs make this analysis easier to understand. The patient can also record meal information and exercise routine. After a two-week period, a quick summary shows how glycaemia is changed by insulin delivery, diet and exercise patterns. Due to this device patients are able to modify their lifestyle if they notice that certain activities increase their glycaemia. The healthcare provider can access to report and modify treatment if necessary. According to its intended use, this software is considered as a medical device.

C. Medicinal products

A medicinal product is defined as any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis [14].

E-health products falling under the definition of medicinal products are less common. However they can be very useful for patient monitoring and treatment as it is shown in the example below. A company recently developed ingestible sensors. These ingestible markers are tiny and can be swallowed by patients. They are made from food and manufactured on silicon wafers. Inside the stomach, fluids activate the sensor and the product sends ultra-low power digital signal through the body. The signal is received by a small microelectronic receiver (a skin patch or a device implanted under the skin). Whenever a patient takes medicine with this microchip, information such as the type and dose of the drug administered and the heart and respiratory rate are decoded and recorded. Thereby, the body’s response to the administration of drugs can be analyzed. This system could change chronic disease management as it provides a decision support for clinicians and improve patients’ outcome thanks to a personalized treatment. These sensors are intended for in vivo administration and used for monitoring of disease that should classify them as diagnostic agents. In vivo diagnostic agents are medicinal products used for diagnosis or monitoring of a disease. Their evaluation is governed by the same regulatory rules and principles as for other medicinal products.

IV. LEGAL AND REGULATORY ISSUES

While developing medical ICT systems, developers are facing an enormous number of technical issues. General concerns are easily identified and already well known and managed by ICT companies [2].
However due to the specific medical purpose of these systems, additional legal and regulatory issues can impact, slow down, or even stop development of new products.

Table II below summarizes the regulatory/reimbursement issues faced by ICT companies for these types of products. Specific regulatory aspects linked to the medical purpose are provided in column 3, whereas general concerns are listed in column 2.

Medical products irrelevant of their status (medicinal product, medical devices, etc.) are regulated with the constant objective of “Good Use”, and regulations are constantly evolving to take into account learning experiences from vigilance cases and proactive risk analysis.

Within that frame, three specific areas of concern have been identified for ICT products designed for medical use:
- The communication lines between users, health professionals, patients, or regulators and other stakeholders need to be defined and/ or clarified. This includes provisions related to the type and extent of information, training of lay users and professionals, limitations for self use, and promotions as well as management of vigilance activities;
- The link between technology and the type of evidence needed to demonstrate quality, safety and performance, avoid misuse and misinterpretation. This includes defining the pertinent clinical endpoints as well as maintenance of confidentiality;
- The economic impact evaluation and reimbursement/pricing models are not yet ready for such products.

This means that developers are highly encouraged to perform risk analysis tailored to the concerned product and its intended use from the very beginning of development to identify and cover all possible failures—not only technical ones which are more easily identifiable. Various other tools are also available to check and improve users acceptability and comfort such as lay users testing, user/machine interface essential requirements checks as proposed in the Machinery Directive in Europe [15].

<table>
<thead>
<tr>
<th>Item</th>
<th>General aspect</th>
<th>Legal and Regulatory aspect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interfaces between users or evaluators, healthcare assessors and providers, healthcare professionals, or even patients</td>
<td>Possible resistance</td>
<td>- Technico-medical information&lt;br&gt; - Training, learning curves&lt;br&gt; - Determine limits for self-diagnostic, self disease management and self follow-up by patients&lt;br&gt; - Vigilance&lt;br&gt; - Promotion/advertising&lt;br&gt; - Ethical issues: human relationship, social links, no patient exclusion</td>
</tr>
<tr>
<td>Technological issues</td>
<td>- Content;&lt;br&gt; - Texts and graphics&lt;br&gt; - Video&lt;br&gt; - Audio, voice capabilities&lt;br&gt; - Copyrights&lt;br&gt; - Infrastructure and network;&lt;br&gt; - Congestion/4G deployment&lt;br&gt; - Mobile way of life (smartphones or equivalent)&lt;br&gt; - Management/IT system upgrades&lt;br&gt; - Data storage and management&lt;br&gt; - Connectivity / data availability, safety and privacy</td>
<td>Quality, safety and efficiency/performance demonstration&lt;br&gt; - Readability/Understandability&lt;br&gt; - Languages&lt;br&gt; - Data monitoring robustness/confidentiality &amp; safety&lt;br&gt; - Interoperability between various coexisting platforms&lt;br&gt; - Collaborations between Industries, including public/private partnerships</td>
</tr>
<tr>
<td>Costs/healthcare reimbursement systems and insurance companies</td>
<td>Operational costs&lt;br&gt; - Telecommunication costs&lt;br&gt; - Healthcare professional training/patient training&lt;br&gt; - Healthcare service provisions&lt;br&gt; - Charges for e-consultation from doctors/institutions&lt;br&gt; - Public/private partnerships</td>
<td>Economic evaluation / reimbursement as there is a lack of consensual reimbursement&lt;br&gt; - Pricing model&lt;br&gt; - Establishment of harmonized standards on already well known and marketed products or products characteristics to ensure consistent high level of quality whatever the manufacturer.</td>
</tr>
</tbody>
</table>

or manual/leaflet testing by consultation with target user populations or groups as required for medicinal products.

Furthermore, developers need to take into account the various local regulations relative to this type of product for the targeted markets.

Establishing an adapted regulatory framework can be done either thanks to:
- Case by case discussions between developers and regulators to check risk analysis and subsequent development plan and testing, as well as definition of retro-controls and specific survey including vigilance activities to be performed on the concerned innovative products;
interoperability and products conformity rules. As example Continua Health Alliance consortium with two hundred and thirty member companies is currently establishing a system of interoperable personal telehealth solutions by:
- Developing design guidelines that will enable vendors to build interoperable sensors, home networks, telehealth platforms, and health and wellness services,
- Establishing a product certification program with a consumer-recognizable logo signifying the promise of interoperability across certified products,
- Collaborating with government regulatory agencies to provide methods for safe and effective management of diverse vendor solutions,
- Working with leaders in the health care industries to develop new ways to address the costs of providing personal telehealth systems [18].

Regarding reimbursement issues, it is also linked to national political considerations. The only way for ICT developers to convince authorities and governments is to develop products with positive cost-effectiveness/performance ratio demonstrated through medico-economical evaluation. Interoperability and collaborations between developers to gain interconnection between systems is a key element to develop telemedicine and convince users and regulators, reducing the costs of connectivity tools and resources.

The European Commission is apparently convinced of the high interest of these technologies and their impact on healthcare cost reduction, as evidence by the action plan currently being prepared for 2012-2020. This initiative is based on the results of a survey taken during Spring 2011, which invited all interested parties to give feedback and opinions on the main benefits of e-Health, barriers and actions to be undertaken [19, 20].

V. CONCLUSION

Once considered futuristic technology, telemedicine is now a reality and is a growing need in medical practices. Facing user interfaces, technological and reimbursement issues, efficient means and adapted regulatory framework to accompany development and innovations as well as evaluation of services in telemedicine are still needed. Various programs are currently running or being prepared to better understand needs, constraints and objective of the various stakeholders (developers, users [patients and professionals], regulators…) implied in the development of these very specific medical products. Close relationship and communication between these stakeholders are key to develop a tailored regulatory framework allowing innovation.

Note: Illustrations of telemedicine, some e-health products, whether classified as a medical device or not, are presented in the text, which are either already on the market or still under development. Products and suppliers’ names have been deliberately removed.

REFERENCES


Special thanks to Alix Dehesin for her active participation to this paper.