

EUROPEAN COMMISSION Directorate-General for Communications Networks, Content and Technology

Digital Industry Competitive Electronics Industry

> Brussels 28/11/2016 CNECT A3

Smart Wearables: Reflection and Orientation Paper

For Public Feedback

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SUMMARY

Smart Wearables offer unprecedented opportunities for tackling pressing societal challenges by providing solutions in the areas of healthy ageing, patient monitoring, emergency management, safety at work, productivity enhancement, energy management of homes and others. The European Parliament Scientific and Technology Options Assessment Panel (STOA) identified wearables as one of the ten technologies which will change our lives. Market prospects for wearables are very promising: wearables shipments are forecasted to increase to \$150 billion by 2026 from the estimated level of \$30bn in 2016.

The most important capacity of wearables is tracking persons' movements, ambient environment, biosignals and much more, all in real time, to monitor, document and augment their lives. Moreover, coupled with advances in the Internet of Things (IoT), virtual reality, augmented reality and artificial intelligence/deep learning, wearables hold the promise of achieving a new level of human connectedness. Wearables, especially in conjunction with smart textiles, are a strong candidate in becoming the new interface between human beings and the digital world, replacing or extending smartphones' and other portable connected devices'. Wearables can unlock benefits of the data economy in numerous areas ranging from healthcare to manufacturing; from education to fashion, and to energy and to security.

This emerging area represents a major opportunity for Europe to regain competitiveness in the ICT devices manufacturing and textiles & clothing, and to rebuild and consolidate a crucial part of the digital technology value chain for future products. Unlike the computer or mobile industries, wearables are not (yet) dominated by established players. European SMEs in electronic components and systems (including organic and stretchable electronics) are especially active in this field. Research and technology organisations are a source of state-of-the-art innovations. European players are actively building prototype systems and solutions in the areas of wearables for health & well-being and smart textiles, with an increasing potential to tap into future high volume markets.

In order to unleash the full potential of wearables in Europe, well-coordinated Research & Innovation, in addition to a legal, regulatory and market framework, is needed, in view of (i) reaching high technology readiness levels, feasibility demonstration and manufacturing of underlying technologies and integrated prototypes, (ii) the building of open platforms for connected wearables and (iii) the development of application areas and related ecosystems.

This paper is prepared by DG CONNECT services. It takes stock of current technological, market and policy developments in the field of smart wearables as well as of the activities supported by the EU's Framework Programmes. An integrated approach is essential to reflect the current status and future orientation of the wearable ecosystem from components to devices and to data platforms and services.

Input is sought from research, industry and other stakeholders on the ideas captured in this document and on the suggested action points for the EU to support further technology development, innovation and deployment.

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1. SETTING THE SCENE

1.1. What are smart wearables?

Smart wearables are body-borne computational and sensory devices which can sense the person who wears them and/or their environment. Wearables can communicate either directly through embedded wireless connectivity or through another device (e.g. a smartphone). The data collected by the wearable device about the user or its environment is processed in a processing unit located locally or in an external server, and the results are ultimately provided to the wearer¹. Smart wearables² may have control, communication, storage and actuation capabilities.³

The International Electrotechnical Committee (IEC) Standardisation Management Board Strategic Group 10 on Wearables has ongoing efforts to clarify the terminology and obtain an agreed understanding of Wearable Smart Devices. It distinguishes between the following categories of smart wearables: near-body electronics, on-body electronics, in-body electronics and electronic textiles. Also, the Moving Pictures Expert Group (MPEG), a working group of ISO/IEC, explores new standardisation needs for wearables. They have developed a conceptual model for wearables (See Figure 1).



Figure 1: Conceptual model for wearable MPEG

According to the MPEG definition⁴, a wearable may contain several types of sensors, integrated as a system on a module. The sensors sense physiological phenomena from the user or from surrounding environment. The wearable processes this information and acts (e.g. display some visual content, play some audio content, send an alert, provide force feedbacks) on the user. The user can interact with the wearable by a set of commands and may do so via the processing unit.

² "Smart wearables" and "wearables" are used interchangeably throughout this note, both referring to those former.
³ This definition is in line with definitions provided in other sources e.g. <u>https://en.wikipedia.org/wiki/Smart wearable_system</u>

¹ <u>http://www.din.de/blob/160444/56136d9f7c1b2d5a6826c844742903db/wearables-data.pdf</u>

ISO/IEC JTC 1/SC 29/WG 11 Coding of Moving Pictures and Audio: http://mpeg.chiariglione.org/standards/exploration/mpeg-wearable

The wearable can also communicate an aggregated set of sensed information and receive data to/from the processing unit.

Wearable devices may allow the user to track his time, distance, pace and calories via a set of sensors in a T-shirt or on smart shoes. Another example can be smart glasses which combine innovative displays with some novel gestural movements for interaction. A classic example of implanted wearable device is a pacemaker or a heart rate monitor intelligent band aid.⁵

1.2. Smart wearables, in continuous evolution

Smart wearables are becoming increasingly pervasive driven by the continuous miniaturisation of electronics; advances in sensor technology, computing power and connectivity; and, an ever stronger capability to embed intelligence in electronic (and photonic) components and systems, ultimately coupled by a reduction in the price of components. Moreover, the use of new materials, designs, energy storage and scavenging technologies, and production techniques provide a strong push factor to improve performance, functionality and usability, as depicted in the graph below.



Figure 2: Wearables architecture, Credit: Korean Ministry of Trade, Industry and Energy

Thanks to the embedded intelligence, connectivity and an ever-increasing usability, wearables offer unique opportunities for condition/activity monitoring, feedback and actuation/delivery services (e.g. drug delivery or stimulation), localisation, identification, personal contextual notifications, information display and virtual assistance. In simple terms, smart wearable devices and applications can monitor, document and augment our lives, and they can be used to assist people in specialised professional and personal activities.

The most broadly used wearables today are smart watches and fitness trackers. However, the list of devices which are being introduced to the market or are yet to come, is much larger. It includes smart patches, textiles, glasses, virtual reality headsets, exoskeletons (wearable robots), as well as smart jewellery (e.g. hearing aid designed in the form of ear rings and smart jewellery to monitor sleep quality).

The following table shows an overview of some applications for wearable technology and the products included within each of those applications.

⁵ ISO/IEC JTC 1/SC 29/WG 11 Coding of Moving Pictures and Audio: <u>http://mpeg.chiariglione.org/standards/exploration/mpeg-wearable</u>

Applications	Product Categories			
Healthcare & Medical	Blood Pressure Monitors Continuous Glucose Monitoring Defibrillators Drug Delivery Products ECG Monitors Hearing Aids	Insulin Pumps Smart Glasses Patches PERS Pulse Oximetry		
Fitness & Wellness	Activity Monitors Emotional Measurement Fitness & Heart Rate Monitors Foot Pods & Pedometers Heads-up Displays	Sleep Sensors Smart Glasses Smart Clothing Smart Watches Others, Audio Earbobs		
Infotainment	Bluetooth Headsets Head-up Displays Imaging Products	Smart Glasses Smart Watches		
Industrial	Hand-worn Terminals Heads-up Displays Exoskeleton	Smart Clothing Smart Glasses		
Military	Hand-worn Terminals Heads-up Displays Smart Clothing	Exoskeleton		

Figure 3: Types of wearable devices and applications. Credit: Areteon

The following vision expressed by Maksim Skorobogatiy, physicist at Ecole Polytechnique de Montreal in Canada on smart textiles, gives a clear idea on the future direction of developments: "We don't want humans to be aware of what they are wearing. It has to be self-contained piece that can charge itself, store energy and perform useful functions. Otherwise, it's an extra burden that nobody needs in our lives. We're moving toward a self-contained textile battery, electronics and sensors, all made with textile thread."⁶

Smart wearables are on the closest line separating humans (the physical world) and the digital world, and will transform our lives and society in the near future. Especially, when blended with virtual reality (VR) and augmented reality (AR) technologies, and communication opportunities offered by the next generation (5G) network, a new level of human-to-human and human-to-machine interconnectedness can be achieved. According to the "Report on Wearable Technology and the Internet of Things" within the next five years users are expected to wear multiple devices allowing them to connect to the internet and to interact with their physical environment⁷.



Figure 4: Augmented reality headset in a factory. Credit: Microsoft

⁶ http://www.livescience.com/18238-smart-clothing-wearable-gadgets.html

⁷ "Report on Wearable Technology and the Internet of Things", Ericson ConsumerLab, June 2016, source: <u>https://www.ericsson.com/thinkingahead/consumerlab/consumer-insights/wearable-technology-and-the-internet-of-things</u>

Some industry experts see wearables as the "missing mate" to the IoT^8 . The study made by Ericsson ConsumerLab reveals that 74 percent of the smartphone users surveyed⁹ believe they will be using wearables to exchange information with other devices and the physical things around them. 60 percent believe that ingestible pills and chips under the skin will be commonly used in the next 5 years – not only to track vital health data, but also to unlock doors, authenticate transactions, to be used as identification and finally control objects.

85 percent of 5000 smartphone users surveyed by the Ericsson ConsumerLab consider intelligent wearable electronic assistants to be commonplace within 5 years. And, one in two believes they will be able to talk to household appliances, as they do to people¹⁰. According to this, artificial intelligence (AI) interfaces will replace the current smartphones in this timeframe. AI will enable interaction with objects without the need of a smartphone screen. Moreover, smart contact lenses, ear implants and wristbands will start to meld the virtual and the real. Pokémon Go, the wildly popular mobile game that transposes characters on to real life¹¹ settings, is actually offering a first experience.



Figure 5: Pokemon Go and Virtual Personal Assistance in a supermarket

The full deployment of wearable devices in new application areas requires further advances to increase functionality, allow conformability and reduce energy consumption. A shift will occur from today's single-function wearables (e.g. rigid electronics, peripheral mobile phone) towards the "*next generation*" of wearables which will go beyond wrist worn devices or 'simple' integration in clothes.

New generation wearables will be flexible, fashionable and invisible. They will embed advanced features such as energy harvesting, efficient power management and very low-power high-performance computing. Moreover, coupled with advances in mobile communication and internet technologies, this field is transforming from the 'world of smart watches and trackers' into a realisation of the 'internet of smart wearables'.

2. ECONOMIC AND SOCIAL OPPORTUNITIES FOR EUROPE

2.1. Wearables help tackle societal challenges

Wearables will have a significant contribution in tackling pressing societal challenges. Wearable technologies for point of care diagnosis or for physiological monitoring can help prevent serious

⁸<u>http://www.techrepublic.com/article/top-iot-and-wearable-tech-trends-for-2016-smartwatches-in-transition-as-</u> <u>smartglasses-rule/</u>

⁹ In 2016, Ericsson ConsumerLab carried out an online survey of 5,000 iPhone and Android smartphone users, aged between 15 and 65, of whom 2,500 were also existing wearable technology owners. The participants were based in Brazil, China, South Korea, the UK and the US. Their views are representative of the opinion of 280 million smartphone users across these 5 markets. Source: https://www.ericsson.com/thinkingahead/consumerlab/consumer-insights/wearable-technology-and-the-internet-of-things

¹⁰<u>http://www.ericsson.com/res/docs/2015/consumerlab/ericsson-consumerlab-10-hot-consumer-trends-2016-report.pdf</u>

<u>report.pdf</u> ¹¹ "Wireless earphones are a harbinger of our budding lives", Madhumita Murgia, Financial Times, retrieved on 9 September 2016. Source: <u>http://www.ft.com/cms/s/0/18620ab0-75bd-11e6-bf48-</u> b372cdb1043a.html#axzz4K4rfoDwu

health problems and contain the rising economic burden for healthcare services. A paradigm shift can be achieved in healthcare by moving away from treatment towards prevention¹².

State-of-the art wearables are able to measure multiple parameters such as heart rate, respiration or bodily movements in real time, allowing an accurate analysis of users' context and biometric data to be performed. Thanks to *data* delivered by wearables, healthcare providers can diagnose health disorders at an early stage, monitor patients and interfere in a timely manner when problems occur. There is already a wide range of wearable devices in the market that track and predict epilepsy seizures or that monitor the glucose level of diabetes patients and support drug delivery. *Haptic* wearables provide sensory replacement or sensory augmentation, used for the rehabilitation of patients with sensory impairment.

Smart technical textiles and clothing can also be life-savers in harsh working environments (e.g. mines or disaster relief) by measuring critical indicators such as respiration, heart rate or dangerous gases in the working environment and providing real time feedback to the user. Smart glasses can help to visualize risk factors (e.g. gas pressure) in industries like oil and gas extraction. GPS trackers integrated in garments or accessories can help locate children or elderly people.

Furthermore, wearable devices which interact with emerging digital products, become part of digital systems, such as in the case of the autonomous car. Imagine a wearable which measures stress or fatigue levels of car drivers: it could communicate this information to a central control system which in turn could trigger a warning message conveyed to the user or even take appropriate action (e.g. not allowing the driver to start the engine).

Wearables offer an unlimited number of opportunities for improving human life.

2.2. Wearables at the heart of the data economy

Data-driven customized services enabled by wearables have the potential to grow exponentially. Today, wearable devices are mainly used for fitness, well-being and health. Diagnosis at point of care and preventive care are expected to enable considerable savings in public finances whilst unlocking new opportunities for products and data-driven services. Moreover, when supported by IoT solutions, wearable-enabled services will facilitate the interaction between patients and healthcare systems, making them faster and more efficient.

There are clear signs that wearables will soon be utilised on a much larger scale, such as in areas of workplace safety, productivity, security, smart houses, emergency response or banking. Thanks to wearables, conventional businesses in medical or sports equipment can be transformed into service businesses, providing assistance for ambient and healthy living or for tracking, measuring and augmenting the performance of sports professionals. Such transformative effects can reach out to many industries including medical, fashion, sports goods, retail marketing, military and entertainment.

¹² "There are already devices that claim to do more than monitor, such as headbands that alert wearers when they become distracted or wristbands that administer electric shocks to smokers who want help quitting. Electronics companies promise to transform medicine with wearables that can treat symptoms or manage care. Devices are emerging that alert people with epilepsy to incipient seizures, help prevent anxiety attacks, and enable blind people to navigate." Source: http://www.nature.com/news/what-could-derail-the-wearables-revolution-1.18263



Figure 6: Application areas and product categories for wearables. Credit Beecahm Research

Moreover, new business areas which do not yet exist may emerge in the 'digital economy', driven by data and algorithms. Real time actionable advice, feedback and information provided by Virtual Personal Assistants can create new revenue streams, especially when bundled with specialised services and hardware.¹³ Smart clothing can be used to monitor the health and safety of workers at the factory floor¹⁴. Haptic wearables provide tactile alerts, alarms and navigation to enable personal coaching and training of athletes.¹⁵ Coupled with VR and AR, wearables offer users new experiences which can trigger a realm of activity areas for arts, creative industries, education or communications.

Some of the vertical industries such as textile and clothing that will be affected by the wearables revolution represent high employment in Europe and have an elevated intensity of SMEs. The introduction of smart materials and digital technology in textile will allow smart textiles to sense, illuminate, communicate, transform energy, monitor health, and even protect from environmental hazards¹⁶, providing them with advanced functionalities. Research and development activities will play a crucial role in keeping the European industry at the forefront of innovation and in securing competitiveness and future jobs.

Another example of a high value sector to benefit from wearables is the pharma industry. It may see its R&D model shift from a proprietary mind-set to one based on open and shared mobile health data, collected with the engagement of users (as already experimented with in clinical trials¹⁷). Mobile health data can enable the development of drugs and help in real-time monitoring

¹³Ten Wearable Technologies and Capabilities That Should Not Be Ignored <u>http://www.gartner.com/smarterwithgartner/10-wearable-technologies-and-capabilities-that-should-not-be-ignored/</u>

¹⁴ <u>http://www.gateone-project.eu/jump-factory-future-smart-shoes-2.html</u>

¹⁵ https://iq.intel.com/wearable-devices-give-athletes-a-personal-performance-boost/

¹⁶ http://www.samsungvillage.com/blog/2016/05/26/trendteller-technology-in-smart-textiles-clothes/

¹⁷ "Mobile health: the power of wearables, sensors, and apps to transform clinical trials", Annals of the New York Academy of Sciences, 2016 source: <u>http://onlinelibrary.wiley.com/doi/10.1111/nyas.13117/full</u>

of treatment effectiveness. There is a need to further improve the quality of data collected from individuals, which calls for boosting R&D efforts in the area of sensors and algorithm development. Moreover, the regulatory approval for the use of this data in clinical trials will be required.

2.3. A multi-billion euro market on the horizon

The wearables market is forecasted to grow into a multi-billion euro business in the next 5-10 years from now. Although forecasts by market intelligence firms diverge, there is an agreement that body-centered technologies are rapidly penetrating in diverse application areas.



Figure 7: Wearable technology market forecast. Source: IDTechEx (2015)

Gartner estimates that the wearable electronic devices market generated \$28.7bn of revenue in 2016. According to IDTechEx, the wearables market will be worth over \$30bn in 2016, and will be growing in three stages: 10% annually to over \$40bn in 2018, but then accelerating through 23% to over \$100bn by 2023, before lowering to 11% and reaching over \$150bn by 2026.¹⁸ This is a major upward revision to the ten-year forecast made last year estimating the market at only \$70 billion for 2025 (see above figure 7).

According to Gartner, sales of wearables will increase from 275 million units in 2016 to 477 million units in 2020. This represents a \$61.7 billion revenue by 2020. According to HIS forecasts¹⁹, unit shipments which are estimated to be at the level of 175 million devices in 2015 will reach 320 million by 2020, representing more than \$40 billion in revenue ²⁰.

 IDC^{21} estimates that watches and bands will dominate the market over the next five years but equally they expect that other form factors such as clothing²², eyewear and hearables will gain importance. In terms of application areas, figure 7 shows the healthcare market for wearables becoming as important as infotainment, followed by fashion ad industrial markets.

¹⁸ http://www.idtechex.com/research/reports/wearable-technology-2016-2026-000483.asp

¹⁹ https://technology.ihs.com/Services/511880/wearable-technology-intelligence-service

²⁰ https://www.idc.com/getdoc.jsp?containerId=prUS41100116

²¹ <u>https://www.idc.com/getdoc.jsp?containerId=prUS41100116</u>

²² According to Gartner smart garments will be the fastest growing category in wearable technologies in the next ten years.



Figure 8: Relative market size by wearable sensor type in 2020. Source: IDTechEx

Forecasts show that there will be over 3 billion sensors in wearable technology devices by 2025, with more than 30% related to new emerging sensor types. The forecast by IDTechEx covers all sensor types used in wearables today e.g. inertial measurement units, optical sensors (including optical heart rate monitoring, PPG-photoplethysmography and cameras), wearable electrodes, chemical sensors, flexible stretch/pressure/impact sensors, temperature sensors, and microphones.



Figure 9: CAGR by sensor type - 10 year forecast (2015-2025). Source: IDTechEx

Most sensors used in wearables today are an adaptation of sensors deployed in automotive or mobile devices. However, with new properties such as flexibility and washability becoming important, further sensor developments will be needed. Chemical sensors are estimated to take the largest share of this new market. The fastest growth is expected in the emerging stretch and pressure sensors, planned to be used in motion detection and healthcare monitoring.

2.4. Research and innovation to unlock the full potential of wearables

Several factors inhibit the uptake of wearables. These include the limited functionality, the low level of comfort and body conformability, short battery life, limited connectivity, lacking interoperability, concern on data security and high production costs. Moreover, there is a lack of convincing use and strong business cases.

Research and development efforts in the area of wearables are thus essential for unlocking innovation and bringing the "next generation wearables" to consumers and professional users. In particular, multidisciplinary research and development in both enabling technologies (e.g.

sensors, materials, energy storage and management, smart system integration) and in other areas such as microfluidics and micro-nano-bio systems is needed. Advances in organic electronics on flexible displays and sensors will allow devices to conform to our bodies and our clothes. This will actually solve major design restrictions by reducing the space required for displays in devices given their thin structure.



Figure 10: i) Responsive LED jacket by utope (Austria) ii) Flexenable OLCD display fby Flexenable (UK)

Future wearables will have to be shapeable, stretchable and washable/cleanable on-demand, e.g. in the case of textile and clothing (a wearable should indeed look like natural clothing because of comfortability, breathability and washability). Automated production techniques need to be developed to directly integrate electronics into the yarn during the production of smart textiles.

Moreover, experimentation and testing in real-world environment is needed when developing and validating the use-cases. Ecosystem building activities (e.g. bringing together the textile and electronic communities or fashion industry) enables addressing of issues like the compatibility of manufacturing practices or design, which have an impact on cost and conformability of final products.

3. EUROPE'S POSITION IN TECHNOLOGY AND MARKETS

3.1. Europe is strong in electronic components and systems in some major markets

Europe is overall well positioned to scope and exploit the potential of smart wearables; spin-off and small companies as well as large companies are very active in the field of electronic textile & garments, wearable electronics, body-worn and personal portable devices. Plenty of opportunities exist in a large number of sectors, particularly in healthcare and medical, fitness and wellness, sports goods, clothing and technical textiles²³ (including personal protective equipment).

Given the high economic potential, wearables' global technology and industry landscape is characterized by fierce competition. Europe is currently lagging behind the US and South Korea in patent filings despite the good performance of some individual companies, according to a recent WIPO report²⁴. This can probably be explained by the presence of industry giants (Microsoft, Samsung, LG, Qualcomm etc.) in these economies, specializing in the current generation of wearable devices (e.g. smart watches, wristbands).

Europe is particularly strong in achieving the integration of complex heterogeneous technologies (e.g. combining microelectronics, photonics, materials, nanotechnology) into multifunctional prototype systems and testing them in the right environment. This is due to the active presence of

²³The size of the global market forecasted for smart textiles in 2022 is \$70 billion <u>http://www.cientifica.com/research/market-reports/wearables-smart-textiles-nanotechnologies-markets/</u>

²⁴<u>http://www.wipo.int/export/sites/www/patentscope/en/programs/patent_landscapes/documents/patent_landscapes/lexinnova_wearable.pdf</u>

universities, RTOs and SMEs combining multi-disciplinary skills and expertise. Moreover, a strong expertise in industrial equipment provides the tools and techniques for testing and characterization of these devices (e.g. mechanical stress, humidity). Typical examples of complex smart systems are found in smart clothing, personal protective equipment and health & wellbeing.

While the market for smart watches is dominated by large non-European players, (in particular Apple and Samsung), some small players in Europe that have critical competences in *technical textile* (including electronic textile) are major players in niche markets (e.g. Clothing+, Smartex and Thuasne). Philips is amongst the world's top three companies which have the highest number of patents and patent applications on wearable *medical devices*²⁵. Moreover, smaller European companies (e.g. WinMedical, Polar Electro, Nuubo and LifeWatch AG) have secured a strong global position in the field of healthcare.

A recent report by Cientifica defines three generations of textile wearable technologies: first generation wearables where a sensor is attached to apparel; second generation products which embed the sensor in the garment; and, finally the third generation wearables where the garment is the sensor (which represents the "next generation" wearables). It argues that the next generation wearables will provide significant opportunities to well-established textile companies for creating value, as this may render the current generation of wearable gadgets by Apple or Samsung obsolete.²⁶ Europe has a good starting point thanks to a strong technical textiles industry. Although, it should be noted that Samsung²⁷ has already entered the smart clothing market. And, if competition heats up²⁸ in this area, take-overs motivated by technology acquisition could follow.

Europe-based companies in the area of electronic components, such as ST Microelectronics, NXP (especially with the acquisition of Freescale) and ARM are prominent players in the area of wearable technologies. European suppliers cover a wide range of products including motion and environmental sensors (e.g. accelerometers, pressure sensors, humidity and temperature sensors), MCUs, MEMS microphones, RFID NFC identification products, processor IP building blocks as well as open-source reference platforms for product design.



Figure 12: Wearable world taxonomy. Credit: Venturebeat

²⁵ Ibid.

²⁶ <u>http://apparel.edgl.com/news/Report--Smart-Textiles-Are-Fashion-s-Fourth-Industrial-Revolution106982</u>

²⁷ <u>https://www.wareable.com/smart-clothing/best-smart-clothing</u>

²⁸ According to the Cientifica report, the market for wearables using smart textiles is forecast to grow at a CAGR of 132% between 2016 and 2022 representing a \$70 billion market.

Furthermore, printed electronics are in demand as an addition, or indeed an alternative, to conventional silicon technology in certain applications. Placing electronic components on plastics and curved surfaces allow acquiring thin, light, and flexible characteristics. Through plastic and organic electronics it is possible to manufacture flexible displays and sensors, which provides freedom of design to producers and increase in user comfort. Europe has major strengths in this area including key players in research, such as the VTT Technical Research Center of Finland and the Holst Center in the Netherlands.

There is also a strong presence of upstream players in Europe who supply the necessary materials (e.g. DuPont for conductive and stretchable inks, or Covestro for adhesives) for plastic and organic electronics. Another important key enabling technology for wearables is energy storage. Although Asian countries are leading in commercial applications in domain, European RTOs (e.g. CEA) work on the development of cutting edge-solutions in thin film and flexible batteries as well as on energy harvesting techniques (e.g. solar and fuel cells).

3.2. Europe has a low rate of adoption but the market growth potential is high

According to the Cisco Global Mobile Data Traffic Forecast²⁹, there were 97 million wearable devices in the world in 2015. The figure below shows the regional distribution of these devices. The North American and Asia-Pacific regions hold the top two positions and together the 70% of the global market. Europe follows in third place and represents around one fifth of the global wearables market. This indicates a lower rate of adoption in Europe especially when compared to the US market of 300 million people.

According to CISCO estimates, there will be 601 million wearable devices globally by 2020, growing fivefold (from the level in 2015) at a CAGR of 44%. Predictions indicate that Asia Pacific will have the largest regional share of wearables in 2020, with a 32% share up from 31% percent in 2015. The North America share of 40% in 2015 is forecasted to decline to 30% by 2020. Europe's share which is currently slightly above 20% of the global market is expected to increase to 30% by 2020, the same level as North America. The number of connected wearable devices in Europe, which is some 20 million today, could grow eight-fold to reach some 173 million units in 2020.



Figure 13: Regional wearables devices share growth. Credit: Cisco 2016

²⁹ <u>http://www.cisco.com/c/en/us/solutions/collateral/service-provider/visual-networking-index-vni/mobile-white-paper-c11-520862.html</u>

As indicated in the aforementioned Ericsson ConsumerLab report, regions with a high number of smartphone owners may be more poised to the rapid uptake of smart wearables, thanks to user familiarity with technology. For wearable medical devices, an ageing population will be a major driver for the uptake of wearables. Moreover, the existence of strong data networks is likely to affect the growth of this segment. With the IoT, fixed and mobile devices — tablets, vending machines and cars alike— will be connected and will work together. To put this into practice at a large scale, such as in a smart city, a unified framework for seamless connection is required. 5G will provide such a unified framework.³⁰

	2015		2020		
	Number of Wearable Devices (K)	Percent of Global	Number of Wearable Devices (K)	Percent of Global	
Asia Pacific	30,403	31.4%	194,669	32.4%	
Central and Eastern Europe	5,006	5.2%	45,850	7.6%	
Latin America	1,828	1.9%	26,083	4.3%	
Middle East and Africa	4,087	4.2%	25,416	4.2%	
North America	38,645	40.0%	180,963	30.1%	
Western Europe	16,748	17.3%	127,644	21.3%	
Global	96,717	100.0%	600,625	100.0%	

Source: Cisco, 2016

Figure 14: Regional wearables devices share growth forecast. Credit: Cisco 2016

Overall, it is likely that Europe will become a leading market for wearable devices. At the same time it could be a main provider of technology and products, and tap into business opportunities. Enabling the market uptake of wearables is highly dependent on multiple factors and requires making progress along a number of action lines in a parallel and coordinated manner.

3.3. Both technological and non-technological barriers hinder market uptake

In order to sustain and further enhance European industry's innovation capacity in this field, research and development efforts should be intensified with a focus to remove bottlenecks in different application areas. Innovation in *hardware* is a high priority since most barriers of adoption are related to the performance, functionality and the manufacturability of wearables.

Major inhibiting factors are observed in component integration, reliability of connectivity, efficiency of energy storage, power management solutions, user interfaces and data security. Overcoming these barriers will enable new businesses to emerge and enhance the position of existing European companies.

3.3.1. Technological challenges

These challenges can be summarized as follows:

- *New component integration methods:* integration and miniaturization of sensors, actuators or power sources which comply with thermal and electrical requirements.
- *New interconnection technologies:* including new technologies for integrating electronics on textile substrates.

³⁰ <u>http://spectrum.ieee.org/tech-talk/computing/networks/5g-taking-stock</u>

- *Integration and assembly technologies:* including pick-and-place techniques for device mounting, stretchable module integration into the fabric or chips placement on the foil using self-assembly principles.
- *Power management and storage*: development and integration of energy related systems (e.g. batteries, photovoltaic cells, etc.) to obtain energy-autonomous, self-powered systems and devices.
- *Manufacturing technology for printed electronics:* developing a scalable and cost-effective manufacturing technology e.g. based on roll-to-roll processing for producing flexible and non-intrusive devices at high volume and consistent quality.

Besides hardware issues, other technical challenges include the seamless hardware-software integration; the development of standard APIs facilitating app creation; open operating systems and cross-platform development (which is needed to enable wearable devices to run on multiple platforms); open communication protocols, ensuring security and privacy (especially for application areas like health and finance); and the development of new communication systems (especially for artificial and virtual reality to make them more realistic and immersive).

Progress should be made in each of these areas in a coordinated fashion to be able to accelerate the product development and market uptake of wearables.

3.3.2. Non-technological barriers

During the Stakeholders Day on Wearables organized by DG CONNECT in December 2015³¹, it was confirmed that besides challenging technology developments, non-technical barriers affect the development and commercialization of wearables. The main conclusion of the event was that it is of paramount importance to build up an eco-system in Europe that includes equipment providers, platform or network operators, content/app providers and end-user/final consumers. It was highlighted that in order to create value there is a need to establish a good understanding of complex interactions between the actors of the eco-system.

Non-technological barriers can be summarized as follows:

- *The absence of standards and test methods*: the development of standards, especially in the area of health and safety, is essential to enable designers and manufacturers to ensure their customers that their products are safe and reliable. Standards are also needed to help industry comply with regulatory requirements (e.g. electrical safety, electromagnetic compatibility, bio compatibility),
- A lack of common understanding and effective cooperation models between eco-system actors: value chain actors include device makers, network operators, content and application providers, textile producers, clinicians, artists and consumers. Insufficient connection and communication amongst them hamper the creation of business value and market acceptance.
- *The development of an appropriate regulatory framework:* a clear regulatory framework providing at the same time freedom-to-innovate and ensuring an appropriate level of protection for users' health, safety, data and privacy is needed. The most important areas³² concerned are data protection, data privacy, free flow of data, liability and consumer protection (e.g. in the field of medical devices).

³¹ <u>https://ec.europa.eu/digital-single-market/news/information-and-stakeholders-day-smart-wearables</u>

³²Debates on regulation, with a focus on privacy, health and safety, data security and privacy have already started both in the USA and the EU. See for example, the US Food and Drug Authorities' initiative/reflection on wearables: <u>http://bit.ly/1lg7x57;</u> the EC green Paper on mobile health: <u>http://bit.ly/29qyBDW</u> and <u>http://bit.ly/1MaFcBn</u>

• *The absence of education and low level of awareness:* this is an essential factor to foster user acceptance which is necessary to make sure that technology is used in a correct manner and for the intended purposes.

Once a solution has been proven to be technically viable, safety, efficiency, end-user acceptance, regulatory compliance, approval for reimbursement and effective marketing are as critical as the preceding phases of proof of concept or product development.

4. MAIN TOPICS FOR ACTION FOR THE EU

According to a portfolio analysis of projects by the 7th Framework Programme in the area of components and systems, the EU provided funding worth \notin 43.5 million to ten projects with a total budget of \notin 63.7 million in the area of wearables. These included eight collaborative projects, a coordination and support action and a pre-commercial procurement project. Among the application areas addressed by the projects, healthcare (the most important), well-being, automotive and decoration, attracted the highest interest. Other areas of interest included lighting, monitoring and sensing, wireless communication and tracking, smart cards, labels and devices. The projects generated in total 3 spin-offs, 24 patents and 48 journal publications (see more details in Annex I).

Public policy can further play a role to help advanced new generation wearables take off and enable their mass adoption. Major areas of potential intervention include grants for collaborative research, support for access to infrastructure and technology transfer, demonstration and piloting activities, as well as ecosystem creation (e.g. between RTOs, app developers, equipment suppliers, creative industries, artists³³ and users). Public policy can also address regulatory barriers (e.g. the protection of privacy, access to data, data ownership, liability, cybersecurity) whilst coordinating the roll-out of new communication infrastructures, such as for 5G, which is required by various applications to operate seamlessly.

4.1. Develop enabling technologies for next-generation wearables

The technologies needed for smart wearables are many, ranging from sensors, actuators, power, processors, connectors and communication functions based on MEMS, organic and flexible electronics, robotics, photonics to advanced materials (e.g. smart textiles). The involvement of multidisciplinary skills and teams is required during the development phase. Manufacturing technologies and equipment have an equally important place in the process. Solution developers typically aim at fast and affordable prototyping leading to final devices that are smaller, smarter, better connected, secure and power-efficient. This would require an open development environment providing interoperability across all components.



Figure 15: Assembly machine for automatic placement of dies and stretchable interposers. Source: http://www.pasta-project.eu/

³³ "Aside from comfort, design and fashion have proven to play an integral part in a person's decision to buy a wearable device". Source: <u>http://tech.co/wearable-technology-2015-obstacles-2015-08</u>

A reliable, cost-efficient and end-user oriented integration of smart systems into body conformable materials (e.g. textile) is a key technological capability for the successful realisation of smart wearables. The ideal combination of reliable functionality, cost efficient manufacturing and a high level of user-friendliness has not yet been achieved. Products typically fall short in one or several of the following: functional performance, durability/reliability (especially connections), efficient production capability, affordable price level, ease of use, comfort (weight, bulkiness, flexibility, skin-friendliness) and ease of care & maintenance (washability, repairability, disposability).

Further development of disruptive wearable technologies, and their integration into reliable, affordable, connected and easy-to-use solutions, is vital for market uptake. This will lead to the validation and deployment of *evolutionary wearables* (e.g. integration of silicon-based electronics, peripheral mobile phone) and prepare the *next (disruptive) generation of wearables* (e.g. weavable, washable, rollable/printable, invisible and fully energy harvesting).

4.2. Focus on building open and interoperable platforms

Platforms for wearables are environments to develop applications and build an ecosystem using technologies which are clearly defined and which work against a set of agreed standards to ensure interoperability and 'plug and play'. They typically address, connectivity, fusion of data & big data techniques, (open) standards, support for a diversity of sensors, connecting sensors in and around the body of the person, smart system integration as well as legal and regulatory issues (such as access to data, confidentiality and critical data protection).

Open platforms are needed both for allowing the developer communities (both hardware and software) to design new functionalities for wearable devices and develop applications which can be integrated into and can function on any device and any data platform. This will play a catalyst role for innovation. Moreover, integrated data platforms will ensure that data from different users, devices and apps can be collected and processed, and then can be fed back to any device in a format that can be understood by the user. Open and interoperable platforms can play a crucial role to unlock networking effects, to help build a business case for developer communities and to maximize the value for users, thus, enabling the mass deployment of wearables.

Wearables are considered the most ubiquitous of the implementations of Internet of Things to date; they contribute to its growing adoption. The Alliance for Internet of Things (AIOT)³⁴, launched by the European Commission and various key IoT players in March 2015, published reports focusing on IoT solutions that integrate key technologies (e.g. nano electronics, organic electronics, sensing, actuating, communication, low power computing, visualisation and embedded software) into intelligent systems. When a wearable ecosystem, for instance in healthcare, is built around an IoT platform, the platform allows accessing the data of tens of thousands of patients, harnessing the power of data analytics and algorithm development for monitoring patients' movements and physiological values, thus providing actionable feedback to doctors, caregivers and patients.

Platforms are developed both by private businesses and publicly funded projects. The European Institute of Technology's Fit2Perform project ³⁵ explores ways for monitoring and predicting the drivers' fitness-to-drive and incentivizing them to drive as long as they are fit. There are also privately owned products. For instance, Fisio@Home provides a telemedicine solution allowing doctors and physiotherapists to remotely monitor the condition of patients with neuromotor or orthopedic problems. Wearable inertial sensors are used to assist the patient in the execution of the rehabilitation exercises at home. A Cloud platform is used for data collection and statistics

³⁴ https://ec.europa.eu/digital-single-market/en/alliance-internet-things-innovation-aioti

³⁵ EIT: European Institute of Technology

visualization.³⁶ A wealth of devices and applications are being introduced to the market to plug sports professionals, factory workers or police officers into the IoT.

Nevertheless, most of the device producers come to the market with their own platform for data collection. In this case, interoperability becomes a primary aspect to underline. Data formats and ontologies would need to be properly indicated and considered.³⁷An open approach to APIs (Application Programming Interfaces) and device intercommunication will play a key role for data accessibility and the interoperability of devices and systems. Moreover, the security of the device and personal data should be ensured at several levels: the device security, the security of the information transmitted from the device to a central hub, and finally, the protection of information stored in the cloud. Standardisation, including for sensors, interfaces and communication protocols, is an important line of activity that can support the development of open interoperable platforms.

Piloting and large scale deployment of the platform in realistic settings is crucial for validating functionality and interoperability (of content, services, use cases and communications across devices) as well as for demonstrating benefits to end-users and developing a dynamic eco-system.

4.3. Perform experimentations for specific applications and support eco-system for cross-industry cooperation

The process of designing and manufacturing wearables and developing wearable-enabled services requires close cooperation between various stakeholders. Any device or solution should be tested during the early stages of their development for user relevance and compliance with regulatory requirements. This requires stepping up efforts for ecosystem creation, boosting cooperation between industries (e.g. electronics, textile, medical devices, construction) and targeted application domains (e.g. healthcare providers, factory managers, trainers of sport professionals).

The various stakeholders needed to design a wearable-enabled healthcare service may include device manufacturers, software engineers, app developers, textile producers and cloud-based service companies as well as healthcare providers, clinicians, caregivers and patients. There is a need to foster a clear understanding of each other's domain, including the user needs and regulatory requirements (e.g. use of hazardous substances, consumer safety), both for hardware and software development and for designing apps and service models. Moreover, each actor should be able to understand how the bigger system functions (e.g. an e-health platform).

There is an obvious shift from single-function wearables towards multi-function devices (e.g. wristbands for tracking steps are used also for sleep monitoring). Such developments create opportunities to develop and launch products, services or solutions which are relevant to a number of deployment scenarios (e.g. in health & medicine, entertainment, well-being, ageing, working environments, customer experiences based on virtual reality scenarios, etc.), targeting impact across multiple sectors (e.g. medical devices, consumer electronics, retail marketing, fitness, sport, industrial production, etc.).

Designing wearable solutions to meet application needs and demonstrating their impact and economic production and sustainability in real environments, is key to success.

4.4. Address showstoppers in standardisation, regulation and communication infrastructure

4.4.1. Support the development of standards in a timely manner

Manufacturers rely on standards and testing methods to prove the functionality, security, safety and interoperability of their products towards customers. The newly developed technologies and

³⁶ AIOTI WG07 Report on Wearables <u>http://www.aioti.org/wp-content/uploads/2016/10/AIOTIWG07Report2015.pdf</u>

³⁷ Ibid.

devices need to go through testing and certification processes to prove compliance with requirements such as electrical safety, biocompatibility, radio frequency exposure, energy efficiency, and data security and privacy of apps. Moreover, IoT and wireless communication standards are necessary to enable interoperability between wearables and their environment (e.g. smart homes, smart buildings) since most wearables will have communication capabilities.

There are ongoing standardisation activities addressing wearables in general³⁸ and the specific field of smart textiles³⁹. Moreover, standards development in the area of electronics and communications contributes to facilitating the adoption of wearables.⁴⁰ An FP7 Coordination and Support Action project "Supporting Standardisation for smart Textiles (SUSTA-SMART)⁴¹" generated standardisation roadmaps and input documents to be presented to relevant standardisation committees. These documents were drafted based on an analysis of the results of 25 EU funded projects including in NMP and ICT (including the Smart@Fire project). Moreover the ICT project SYSTEX contributed to the work of CEN TC 248/WG31 through the partner Centexbel (the Belgian Textile Research Centre).

Technology is moving forward fast and steps should be taken to ensure that the standardisation process is adjusted to the pace of innovation. Closer links should be created between R&D activity and standardisation. There is also a need to adapt existing structures for standardisation to cover areas of technological convergence (e.g. textile and electronics).

4.4.2. Provide a clear and innovation friendly regulatory framework

Public policy should find solutions for the *privacy & security* concerns of end-users and ensure that users understand and trust wearables and the platforms on which they operate. Service providers, such as in health or care services, need to collect personal data and share it with nurses, doctors, or caregivers⁴²: necessary guarantees should be provided to users with regards to their privacy concerns. Devices with imaging or video shooting capability could also cause extra concerns especially when they capture images of passers-by.

Wearables create new challenges in terms of *liability*. It may be difficult to determine who is liable (device manufacturer, user, app developer, network service provider or user) in case a safety-critical device fails and causes harm to the user. Who is responsible if a factory worker wearing smart-glasses gets distracted and has an accident? Or, when the deficiency of an insulin delivery device leads to a dangerous medical situation? Moreover, rules should be reviewed in view of cyber-attack threats.

Restrictions on the *free flow of data*, including legal barriers on the location of data for storage and/or processing purposes, may hamper the delivery of high value services bundled with wearable devices. Furthermore, the access of healthcare providers or of researchers to data (e.g. of patients with similar medical conditions) may revolutionize medicine, but this should be accompanied by individual privacy and security safeguards⁴³. The Commission's free flow of data initiative provides an important opportunity to address data location restrictions and emerging issues of data ownership, access and re-use as well as liability in the context of wearable devices.

³⁸ E.g. IEC SMB SG 10 – "Wearable Smart Devices" and IEEE Working Group on Wearables working on the "P360™ (CES/SC) Standard for Wearable Consumer Electronic Devices - Overview and Architecture"

³⁹ E.g. CEN/TC 248 WG 31 "Smart Textiles" and CEN CLC BT/WG 8 on "Protective textiles and personal protective clothing and equipment"

⁴⁰ E.g IEEE 802.15.6[™] Standard for Wireless Body Area Network (WBAN); IEEE 802.15.4[™] Standard for Low-Rate Wireless Personal Area Networks (LR-WPANs), IEEE 11073[™] Personal Health Devices, ISO TC21 and (CEN) TC251 on Health Informatics.

⁴¹ <u>http://cordis.europa.eu/project/rcn/104758_en.html</u>

⁴² AIOTI WG07: Report on Wearables <u>https://ec.europa.eu/digital-single-market/en/news/aioti-recommendations-</u> <u>future-collaborative-work-context-internet-things-focus-area-horizon-2020</u>

⁴³ "Accessing and Using Data from Wearable Fitness Devices", Harry Rhodes, source: <u>http://bok.ahima.org/doc?oid=107442#.V-E8LHrIZak</u>

For devices used in healthcare applications, the accuracy, reliability and safety of wearable *medical devices* will be of paramount importance. Clinical trials need to be carried out and certifications may need to be issued if they are qualified as a medical device. There is an ongoing debate in the US on whether wearable devices for health and well-being should be subject to regulation as medical devices, or more properly considered as a recreational, fitness tools.⁴⁴ In Europe, discussions are concentrated on the new EU regulatory framework on medical devices⁴⁵.

<u>Clear</u>, understandable and transparent rules are crucial to gain the trust of consumers in the performance and safety of new technological solutions. For businesses, an effective regulatory environment determines the framework conditions with regards to the freedom of innovation, interoperability and competition.

4.4.3. Improve mobile network speed and capacity

The increasing number of wearable devices is expected to generate a significant burden on *mobile data traffic*. As of the end of 2014, 100 million or so wearable devices were generating 15 million gigabytes of monthly traffic on what is a physically finite portion of the electromagnetic spectrum, with the number expected to increase fivefold by 2019⁴⁶. Governments have a leading role to play when it comes to easing congestion by freeing up spectrum.

The true era of virtual reality will only fully take off once the technology frees itself from bulky PCs and can run smoothly on mobile devices. Streaming full HD or even 4K virtual reality imagery places extreme demands on bandwidth, while real-time interactions emphasise the need for minimum latencies. According to an expert at Qualcomm, mobile virtual reality requires fibre-like speed in wireless⁴⁷. Virtual reality supported by smart wearables (thanks to sensors capturing hand gestures and translating them into VR apps) will enable interactions (e.g. a factory training programme, collaborative artistic creations) between users located in different parts of the world. *5G communication systems* will become an enabling factor for the IoT and VR applications enabled by wearables to function.

The Digital Single Market Strategy and especially the Digitising European Industry (and the Free Flow of Data) initiative tackle most of these issues. Close monitoring, consultation with the stakeholder base in the wearables ecosystem and cooperation across Commission services will be needed to understand the impact of regulatory initiatives on innovation and business.

4.5. Opportunities and challenges

The Information and Stakeholders' Day⁴⁸ on Wearables (Brusels, December 2015) attracted more than 130 people and some 15.000 tweet interactions, clearly showing a high level of interest in the area of wearables and the existence of a committed stakeholder base in Europe.⁴⁹ (See Annex II for the event report). Inquiries of the European Commission with research and industry stakeholders show that besides providing support for research and development (e.g. new components, materials, sensor integration), there are expectations on policy-makers to help address barriers that inhibit the commercialisation of prototypes and demonstrations.

A major difficulty faced in efforts for bringing advanced smart wearables to the market is related to meeting product regulations. In most cases standards, on which industry could rely to ensure conformity with health and safety requirements, are in the development stage or are simply nonexistent. Furthermore, stakeholders involved in the design and development of wearables belong often to domains which have traditionally been disconnected one from another (e.g. medical

⁴⁴ FDA Declares 'General Wellness' Devices Exempt From Regulations, <u>http://www.raps.org/Regulatory-Focus/News/2016/07/28/25463/FDA-Says-%E2%80%98General-Wellness%E2%80%99-Devices-Exempt-From-Regulations/ Regulations/ ⁴⁵ http://www.raps.org/Regulatory-Focus/News/2016/07/28/25463/FDA-Says-%E2%80%98General-Wellness%E2%80%99-Devices-Exempt-From-Regulations/ ⁴⁵ http://www.raps.org/Regulatory-Focus/News/2016/07/28/25463/FDA-Says-%E2%80%98General-Wellness%E2%80%99-Devices-Exempt-From-Regulations/ ⁴⁵ http://www.raps.org/Regulatory-Focus/News/2016/07/28/25463/FDA-Says-%E2%80%98General-Wellness%E2%80%99-Devices-Exempt-From-Regulations/ ⁴⁵ http://www.raps.org/Regulatory-Focus/News/2016/07/28/25463/FDA-Says-%E2%80%98General-Wellness%E2%80%99-Devices-Exempt-From-Regulations/ ⁴⁵ http://www.raps.org/Regulatory-Focus/News/Re</u>

⁴⁵ <u>https://blmredblog.com/2016/01/20/health-data-from-wearable-devices-and-apps/</u>

⁴⁶ http://www.nature.com/news/what-could-derail-the-wearables-revolution-1.18263

⁴⁷ http://eandt.theiet.org/magazine/2016/03/mobile-virtual-reality.cfm

⁴⁸<u>https://ec.europa.eu/digital-single-market/en/news/information-and-stakeholders-day-smart-wearables-report-</u> available

⁴⁹ Presentations and the event report can be found at: <u>https://ec.europa.eu/digital-single market/news/information-and-stakeholders-day-smart-wearables</u>.

equipment and textile & clothing industries). Digitisation stimulates convergence between disciplines and industries. For instance, when making the textile material choice for a smart t-shirt, one may need to look both at electrical properties of the material and at health & safety requirements e.g. dermal exposure to hazardous substances. If the device has medical functions, certification and regulatory approval may be needed. Another factor which may come into play is aesthetics, comfort and ergonomics (e.g. for consumer-oriented products).

Wearables are human-centric devices which are designed to very often assist and guide individuals in looking after their health or in carrying out their private and professional activities. As their functions and benefits are human-centric, the associated risks are also directly linked to persons (e.g. privacy, safety). Therefore, wearables will get acceptance from users as long as their benefits are maximised and risks are eliminated (or compensated for). There are mixed beliefs amongst users, industry and markets as regards the future of wearables. Some market forecasts on future sales and market uptake diverge largely based on different scenarios on user acceptance and market uptake. At the same time, opportunities are abundant and are supported by concrete indicators, such as the demos developed in publicly funded research and development projects showing significant benefits for the society and economy.

Government funding for experimentation and prototyping activities in test beds could enable and nurture interaction, cooperation and co-creation between different actors (e.g. electronics, textile, fashion designers and users) to validate use cases for specific applications and to monitor and tackle impact on sensitive issues like security and privacy. Research and innovation programmes favoring ecosystem creation could also help achieve agreement on guidelines and standards to address regulatory conformity right at the beginning of the design phase. The training of engineers is also a key issue and could be facilitated by sharing best practices or tailored education programmes. Standardisation has a key role for providing manufacturers with the reassurance that their products will be compliant with regulatory requirements whilst increasing consumer trust in new technological solutions. Standards will also enable interoperability between devices including for interfaces, communication and data formats. Moreover, the legal framework in EU Member States may need to be reviewed so that a user travelling to another country with his health-monitoring device can still benefit from the services of the provider based in his home country.

Resolving the hardware challenges is only one side of the coin. Wearable devices will run on data platforms linking manufacturers and users a broad ecosystem (e.g. app developers, users, healthcare providers, insurance companies, trainers, factory managers). Therefore, developing open innovation platforms for both hardware and software and app developers could help accelerate innovation, such as by creating new functionalities or security and privacy solutions applicable across multiple sectors. Moreover, data platforms will allow integrating wearables with other technologies (e.g. cloud computing, big data, AI), nurture ecosystems and cross-sector cooperation, and provide the sufficient scale for the creation of new businesses and services.

5. PREPARING THE FUTURE

European projects funded in the field of smart wearables have led to prototypes and demonstrators which show concrete benefits for human life. Today the project owners strive to overcome lack of investment to validate cost-effective working prototype systems and regulatory barriers to reach the market. Public investments in research offer a high return in terms of economic value and improvement of the quality of life. This return can be particularly high if research is complemented with activities targeting higher TRLs (e.g. demonstration in operational environment, experimentation in real life settings) to test the real use cases and impact of new technologies on the society. Such support would help accelerate time-to-market and stimulate user acceptance. Efforts spent in this direction will provide significant opportunities for achieving European leadership in digital technology value chains and platforms.

The European Communication on Digitising European Industry initiative, issued on 19 April 2016, puts a strong emphasis on testing and experimentation activities on large scale pilots to validate use cases for digital technologies. An early test of this innovation model is being carried

out via the Large Scale Pilot on "Wearables for smart ecosystems"⁵⁰. The proposal called "Management Of Networked IoT Wearables – Very Large Scale Demonstration of Cultural Societal Applications (MONICA)" has been selected, after evaluation, for an EU grant amounting to \notin 15 million. MONICA aims to demonstrate a large scale IoT ecosystem, based on open standards and architectures, which uses innovative wearable and portable IoT sensors and actuators to offer a multitude of simultaneous, targeted applications. All ecosystems will be demonstrated in the scope of large scale city events through integration of Situational Awareness and Decision Support tools for organisers, security staff and sound engineers.

Europe has an excellent research base and vibrant industrial ecosystem (e.g. organic and printed electronics, MEMs, smart textile) to tap into opportunities in the area of smart wearables. The challenge ahead is to bring these capabilities into products and services which will create societal and economic value. A considerable number of technological advances in this area find their origin in Europe. However, as technologies come to maturity, the market race for exploring their commercial potential is heating up. Several large international companies in the PC and mobile sectors – having identified wearables as a new growth area - are taking bold steps to acquire players in smart wearables and textiles. Mobile phones have shifted from being communication devices to computers, and are today converging with IoT and VR, which make wearable companies a target for acquisitions.

If Europe wants to benefit from this emerging field for the creation of industrial growth, start-ups and employment, a good step forward would be the design and implementation of an ambitious research & innovation agenda which fosters cross-disciplinary and cross-industry partnerships.

This agenda should support the development, demonstration and testing of new products and solutions to tackle real life challenges.

⁵⁰ Large Scale Pilots IoT-01-2016: the Innovation Action called closed on 12 April 2016. Source: <u>https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/iot-01-2016.html</u>

NEXT STEPS

The European Commission seeks for input from all interested stakeholders to complete this Reflexion and Orientation paper. This will be used for the elaboration of future EU support measures in the areas of research & development, innovation and market uptake of smart wearables.

Stakeholders' input would be particularly welcome on the questions of technology development, ecosystem building and mapping, piloting and testing activities, training and skills development, and exploitation of research results, within the framework of the Horizon 2020 and beyond. Moreover, input on horizontal issues, related to R&I, e.g. regulation, standardisation, networks and infrastructure) would also be welcomed.

The written input and comments should be sent by 15 January 2017, to:

Dr Andreas LYMBERIS: <u>Andreas.Lymberis@ec.europa.eu</u> and

Mr Gökalp GÜMÜŞDERE: Gokalp.Gumusdere@ec.europa.eu

ANNEX – 1 WEARABLES PORTFOLIO ANALYSIS

1. PROJECT PORTFOLIO

10 projects related to smart textiles, flexible and wearable electronics, have been funded under FP7-DG CONNECT-Components & systems. They have been analysed in order to gain an indepth understanding of the relevant work, developments and problems found in this area.

1.1. Projects

- 10 projects: 8 CP projects, involving research and development, 1 CSA (Coordination and Support Action) project and 1 CP-CSA (a Pre-commercial procurement) project. The list of these projects is given in Annex I.
- Total Costs: 63.7 M€
- EU contribution: 43.5 M€ (68% of the total cost)

1.2. Clustering

The classification based on the addressed technologies led to consider 3 main sub-groups (see Figure 1) focusing respectively on:

- Integration of electronics, mainly lighting devices (LEDs, OLEDS) and sensors (photodiodes, thermocouples, RFID tags), in textiles and stretchable substrates.
- Development and integration of electronics, chips, displays, batteries, PV cells, etc. in flexible foil substrates.
- Wireless communication between integrated devices (in tags, implants) with a control system⁵¹.

These sub-groups nevertheless are strongly interrelated through common challenges and approaches (e.g. integration, miniaturization, roll-to-roll production, etc.)

SYSTEX is a CSA project which aimed to bring partners involved in European projects "Wearable electronics embedded in textiles" together in order to group the results of the efforts made in these projects, therefore it is not included in any of the technological groups.



Figure 1: Projects clustering

⁵¹ Smart@Fire has been included in this group since the PCP (Pre-commercial procurement) process is focused in the integration of ICT solutions (GPS system) in smart personal protective equipment for fire fighters and first responders as a concrete business case

1.3. Participants

94 different organisations (85 receiving EU funding) participated in the projects. More information and graphs about participants and budget can be found in Annexes II and III.

- Types of participants: 34% RES (Research Centres), 28% IND (Large Industries), 20% SMEs (Small and Medium Enterprises), 11% HES (Higher Education Organizations) and 7% others (Public Organizations, Associations, etc.).
- 12 participants withdrew the consortia during the projects (50% IND, 33% SMEs, 17% RES) and 12 participants entered (58% SMEs, 42% IND).
- Coordinators: 40% IND, 30% RES, 20% HES, 10% PUB. No SME.
- 10 organisations have participated in more than 1 project. Fraunhofer-Gesellschaft zur Foerderung der Angewandten Forschung E.V. (Fraunhofer) and Commissariat à l'énergie atomique et aux énergies alternatives (CEA) did both participate in 6/10 projects and received 19% of the total EU funding.



Type of participants

Total costs per type of participant and per project



1.4. Geographical location



Figure 2: Geographical distribution and EU funding per participant

Figure 2 gives the geographic distribution of the participants. The size of the circles is proportional to EU funding received by the participants. Participants in the consortia come from **18** different countries.

2. PORTFOLIO ANALYSIS

Technologies and demonstrators' information and data have been extracted mainly from the Description of Work and the Final Project Report. The Final Review Report has been used in order to assess technologies and demonstrators developments.

2.1. Objectives

The main objectives shared by almost all the CP projects are:

- Roll-to-roll manufacturing process
- New interconnection technologies (due to the use of non-usual substrates)
- New component integration methods
- Low cost (therefore a high volume production is required for example to produce high number of RFID tags for a supply chain management or for disposable systems such as smart packaging labels).
- Development and integration of energy related systems (e.g. batteries, photovoltaic cells, etc.) to obtain energy-autonomous, self-powered systems and devices.

2.2. Technologies

Figure 3 shows the number of technologies (segregated in Devices and Systems, and Processes) developed and the number of projects in which these technologies are developed. Most of the effort is focused on integration and related categories such as electrical interconnections devices and processes.



Figure 3: Number of technologies developed and number of projects in which these technologies are developed

2.3. TRL/MRL analysis

TRL (Technology Readiness Level, ranging from1 to 9) and MRL (Manufacturing Readiness Level ranging from 1 to 10) are indicators of the level of development achieved by technologies, systems or fabrications processes. TRL and MRL values for the demonstrators developed in the projects have been scored using the information and assessment provided by the reviewers in the Final Review Report.

26 demonstrators have been analyzed. Most of them range from TRL 3 (experimental proof of concept) to 5 (technology validation in relevant environment). Concerning MRL values demonstrators range from 2 (manufacturing concepts identified) to 4 (Capability to produce the technology in a laboratory environment) as can be seen in figure 3.

1 demonstrator stands out from the rest. It is a smart bandage for renal function monitoring comprising sensors and electronics. It reached an **8 MRL** value (i.e. Pilot line capability demonstrated/Ready to begin low rate production) and it is already on the market (LED version). Another interesting development was not a planned demonstrator *per se*, but a basic bare die device which can be automatically assembled on the conductive yarns in a roll-to-roll process, and subsequently customized with different types of devices such as LEDs and sensors. Both systems have led to the creation of a corresponding spin off.



End TRL/MRL

3. CONCLUSIONS

3.1. Participants/Budget

SMEs could be considered "underfunded" in comparison with the rest of participants categories. SMEs represents 20% of the participants, however the funding received by these organizations represents only 10% of the total EU funding. None of the SMEs participate as a coordinator.

3.2. Technologies

A wide variety of devices and systems have been developed in these projects. Also, a great effort has been made regarding the development of roll-to-roll fabrication processes.

Electronic development and integration in flexible foils have been achieved in an automated way, although device fabrication yields need to be improved to reach a higher manufacturing level, and fabrication costs should be reduced to be successfully introduced into the market.

There is an inherent difficulty in integrating electronic components into textiles since due to the characteristics of textile materials (flexibility and stretchability) the location of the connecting points vary in a not fully controllable manner. This problem has not yet been solved and manual steps keep being a technological barrier. More work is needed to achieve an automated roll-to-roll process for electronics integration in textiles.

Applications

The project addressed in their large majority system integration and fabrication processes & technologies that could impact more than one application. Among the targeted applications, healthcare and well-being received most of the effort to test and validate technologies & prototype systems. Other more general applications like monitoring & sensing, lighting and smart labels devices have been also addresses as cases studies which could indirectly linked to other sectors like transport, decoration and security.



Results

The projects' results have been successful in progressing technology and system integration beyond state of the art as well as testing and validating new processes and prototype solutions. A high number of dissemination activities, articles publications and newsletters have been released. Finally very important foreground knowledge has been protected with patents, especially in technology design and textile integration of electronic and light components.



Figure 5: Number of projects' patents and publications per M€ Funding.

Annex: List of projects

Project	Title	Total costs	EC funding	Duration (months)	Start date
i-Tex	Intelligent and luminous textiles	4,484,497	2,900,000	42	01/10/2011
PASTA	Integrating Platform for Advanced Smart Textile Applications	8,789,263	6,500,000	48	01/10/2010
PLACE-it	Platform for Large Area Conformable Electronics by Integration	16,185,418	10,881,000	46	01/02/2010
Chip2Foil	Ultra-thin chip integration process for low cost communicative polymer foils	4,623,404	2,980,000	40	01/01/2010
Interflex	Interconnection technologies for flexible systems	5,466,966	3,494,966	47	01/01/2010
Smart-EC	Heterogeneous integration of autonomous smart films based on electrochromic transistors	7,255,666	5,100,000	48	01/09/2010
SELECT	Smart and Efficient Location, identification, and Cooperation Techniques	4,607,280	2,850,000	42	01/09/2010
WiserBAN	Smart miniature low-power wireless microsystem for Body Area Networks	9,638,652	6,899,035	48	01/09/2010
Smart@Fire	Integrated ICT Solutions for Smart Personal Protective Equipment for Fire Fighters and First Responders	2,269,600	1,507,173	39	15/11/2012
SYSTEX	Coordination action for enhancing the breakthrough of intelligent textile systems (e-textiles and wearable Microsystems)	848,385	800,000	39	01/05/2008