

Opinion of the European Economic and Social Committee on Promoting the European single market combining biomedical engineering with the medical and care services industry

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On 10 July 2014, the European Economic and Social Committee, acting under Rule 29(2) of its Rules of Procedure, decided to draw up an own-initiative opinion on

Promoting the European single market combining biomedical engineering with the medical and care services industry.

The Consultative Commission on Industrial Change (CCMI), which was responsible for preparing the Committee's work on the subject, adopted its opinion on 24 March 2015.

At its 507th plenary session, held on 22 and 23 April 2015 (meeting of 23 April), the European Economic and Social Committee adopted the following opinion by 135 votes to 1 with 2 abstentions.

1. Conclusions and recommendations

1.1. Biomedical Engineering is not simply a subset of modern medicine. Modern medicine predominantly secures important advances through the use of the products of biomedical engineering ⁽¹⁾.

1.2. The biomedical engineering industry will become increasingly important due to technological development and the potential of new techniques to enhance care and rehabilitation, representing a major step forward in terms of healthcare and of quality of life. Of course this is not the only industry that is relevant here, but it is one that is becoming more and more important.

1.3. Europe is facing rising demand for quality, affordable, safe and permanently reliable health services at a time when public spending is under pressure. With an expanding elderly population and shrinking tax base, it is time for the European Union to rethink its healthcare systems to make them universally accessible, efficient and sustainable by providing sufficient resources.

1.4. For a healthy and well cared for population in the 21st century we need systems engineering approaches that redesign care practices in line with changing needs and integrate local, regional, national, and global health IT networks.

1.5. Access to health and care services is to be considered a fundamental right. The EESC underlines the importance of closely involving potential users of biomedical engineering products — in particular patients and their families, but also medical and care personnel — in decision-making processes to determine together with biomedical engineering experts the direction of biomedical engineering research and the subsequent design of products and services, so that they respond to real needs and preferences, can be easily managed, and thus better serve their purpose. Issues of accessibility, safety, possible dependency and data protection also need to be taken into consideration.

1.6. Access to biomedical techniques and related services should be promoted, especially in those countries with a significant deficit in these areas. Although some funding has already been allocated to health measures linked to ageing, e-health, health promotion and training, we strongly recommend increased use of the Structural Funds in the area of health-related well-being.

1.7. The establishment of a single market integrating biomedical engineering with the medical and care services industry, in combination with ICT and systematic approaches to health informatics, including the acquisition, management, and use of information in health, and telemedicine, will have tremendous advantages for the European Union and greatly enhance the quality and efficiency of medical care for all.

⁽¹⁾ J.F. Kennedy, André C Linnenbank, EAMBES (EESC hearing).

1.8. The EESC supports better deployment of 'more Europe in health', with four essential strands:

- harmonisation of existing legislation;
- implementation of existing legislation;
- research, development and innovation activities;
- access equality, with a special focus on vulnerable sections of society.

1.9. The EESC advocates and recommends:

- fully ensuring healthcare and equal access to healthcare for all;
- providing continuing support for health issues in the education system and in research and innovation activities;
- encouraging policy-makers to establish a system for communicating about innovation;
- providing better information for and from the market;
- sharing information with the public at large to promote trust in innovation;
- having both horizontal and vertical communication;
- reinforcing market controls for ensuring consumer safety;
- reinforcing the process of medical device standardisation;
- incorporating ePrescriptions into the national strategies of all EU countries;
- guaranteeing accessibility, interoperability and open sources for eHealth;
- changing the system to outcome measurement instead of micro financial controlling;
- giving more visibility to the scope and role of the MD industry in the economy and in healthcare, e.g. an own category for Biomedical Engineering and Care Services under the: <http://ec.europa.eu/research/health> homepage;
- consolidating funding for research and development and product development ⁽²⁾;
- funding innovation management, dissemination and exploitation;
- reviewing all systems for reimbursement and funding, since the present situation is mostly very difficult and might cause a major loss of skills and professionalism.

1.10. Europe should follow the US example and recognise the discipline as a stand-alone science. This would also help to foster the international competitiveness of European companies.

1.11. The EESC supports the goals of the EU:

- to improve people's health by making life-saving information available using eHealth tools;
- to increase healthcare quality and access by making eHealth part of health policy and coordinating EU countries' political, financial and technical strategies;
- to make eHealth tools more effective, user-friendly and widely accepted by involving professionals and patients in related strategies, design processes and in implementation.

⁽²⁾ Manfred Bammer, head of Biomedical Systems, AIT (EESC hearing).

1.12. The training and employability of biomedical and biomolecular engineers are strategic factors in the development of an advanced society, since the close relationship between productive activity and human health is now increasingly central to social organisation and, therefore, in hardware producing and services industries.

1.13. The main activities requiring specialists today in biomedical engineering are:

- manufacturing, marketing and evaluation of medical devices and equipment (for prevention/diagnosis/treatment/rehabilitation), special materials, implantable devices, prostheses and robotic systems for biomedical applications;
- strategies relating to the implementation and servicing of biomedical equipment and systems;
- clinical engineering services in public and private health facilities, in the world of sports and entertainment;
- telemedicine and telematics applications in health-related diagnosis and treatment;
- medical informatics, namely health information systems and software for processing biomedical and bio-imaging data;
- biotechnology and cell engineering;
- the pharmaceuticals industry and the food industry, to analyse and quantify the interaction between drugs/substances and biological parameters;
- the manufacturing industry in general: ergonomics of products/processes and impact of technologies on human health.

1.14. The European and national regulatory framework was unable to keep up with the fast pace of technology change in particular in additive manufacturing, which is why there is a twofold need for regulation: On the one hand, specific regulation to deal primarily with standards and certification and on the other hand, a re-evaluation of existing legislation from the AM perspective.

1.15. One major concern is that medical devices are considered industrial products and thus may receive certification from private entities. For this reason, a more specific and adequate guarantee of quality certification needs to be developed. The EESC supports the European Parliament resolution of 2 April 2014 on medical devices.

1.16. Special attention should be paid to the role of space research programmes, which also can lead to key innovations in the medical field.

1.17. The EESC recommends that the Commission initiate a study of biomedical engineering in Europe analysing its benefits for industry and healthcare services. It is crucially important to analyse the interrelationship between policies that affect the health market and those concerning the biomedical engineering industry.

1.18. A time frame of at least 10 years is needed to realise a coherent healthcare programme striving towards efficient applications of novel technologies in healthcare. This is at odds with the European Commission terms of only five years, meaning that visions and strategies change continuously. A stable vision and fixed objectives are greatly needed as the cornerstone for efficient healthcare in the future. It is necessary to ensure healthcare for all and equal access to that care through product and service innovation, as well as a long-term perspective and consistent policies and strategies to realise the objectives.

2. Introduction

2.1. 'Our shared ambition should be that we can ensure every European citizen to be digital, connected and healthy. And that Europe will take this opportunity and gain the lead in this growing and highly innovative market': Neelie Kroes, former European Commission vice-president.

2.2. 'Biomedical engineering is a cross-disciplinary science based on medicine, biology and engineering. It is fundamental for a variety of highly innovative technologies and products or processes of the healthcare sector. Biomedical engineering should be understood as a stand-alone discipline to better utilise resources and fully realise the corresponding opportunities. It is thus important that the EU recognises the full potential of biomedical engineering and consequently promotes collaborative research in this field'. This was how biomedical engineering was defined at the Expert Policy Workshop on Biomedical Engineering held at the European Parliament on 27 March 2012.

2.3. Biomedical engineering, or medical and biological engineering, encompasses such areas as biomedical electronics, biomechatronics, bioinstrumentation, biomaterials, biomechanics, bionics, cellular, tissue and genetic engineering, clinical engineering, neuroscientific engineering, diagnostic and medical imaging, orthopaedic bioengineering, rehabilitation engineering, system physiology, bionanotechnology and neural engineering.

2.4. Biomedical Engineering is a key sector for European competitiveness. Some data ⁽³⁾ are set out below:

- At present EUR 100 billion market size (it is estimated the world market will amount to USD 514 billion by 2020);
- 25 000 companies, of which 90 % are SMEs;
- 575 000 jobs;
- 1 sector in patent applications: 10 412 in 2012;
- Short product lifecycle (~ 18 months)
- In the Horizon 2020 framework, the EU channels EUR 8 billion into health research (out of EUR 80 billion over 7 years).
- In the IMI Europe's partnership for health (2008-24 partnership), EUR 5 bn (EC 50 %, efpi-a 50 %) ⁽⁴⁾.

2.5. The ageing of society, increasing severity of chronic diseases and growing healthcare costs are becoming global challenges. As technology plays a key role in the health and care services sector, research, innovation, safety issues and development activities in biomedical engineering, relating to medical and care services, are major challenges and of increasing socioeconomic importance in today's society.

2.6. Good health is essential for well-being, economic prosperity and sustainable development. The health sector is driven by scientific and technological progress, which affects employment, innovation, sustainable development and growth. According to the World Health Organisation (WHO), health technology is important for increasing the quality of health and care services, including solving health problems and improving the quality of people's lives.

2.7. Among the important challenges are:

- the focus on enhanced prevention and early diagnosis by using new technologies;
- efficiency-based medicine not just evidence-based medicine (e.g. implementing new processes in healthcare via technology support such as tele-services);
- proof of cost-efficiency, which is often very difficult because of the heterogeneous financing systems in the healthcare domain in Europe;

⁽³⁾ Ruxandra Draghia-Akli, Director Health, DG Research and Innovation, European Commission (EESC hearing).

⁽⁴⁾ See footnote 3.

- multi-stakeholder situations and competing interests between different stakeholders;
- depending on the medical device classification and invention, the fact that it can take up to 10 years from the idea stage to reimbursement;
- facilitating the adoption of cost-effective measures, not least those based on emerging and possibly even remote technologies, by establishing appropriate reimbursement systems.

2.8. The new field of precision medicine ⁽⁵⁾ can address the following:

- the fact that every patient is different: unique sequences;
- the need for tailor-made medicine;
- colonies of cells are genetically different and co-exist in cancer;
- sub-colonies of cells emerge after treatment by selection or by new mutations;
- treatment efficacy depends on genetic make-up;
- sequencing-based prognosis can adjust severity of treatment.

2.9. Although the discipline of biomedical engineering was recognised in 1998 by the 4th Framework Programme for Research and Innovation, current EU policy in this area is fragmented. Biomedical engineering in the United States is treated as a separate discipline, with distinct methodological and analytical techniques.

2.10. The OECD reports that overall health spending accounted for 9,3 % of GDP on average across the OECD countries in 2012, whereas in the United States it accounted for 16,9 % of GDP, which is the highest proportion in the OECD ⁽⁶⁾. In Europe, an average of 10,4 % of GDP is spent on healthcare. Of this figure, around 7,5 % is allocated to medical technologies, with significant differences between the EU Member States. Furthermore, expenditure on medical technology in Europe stands at around EUR 195 per capita (weighted average), compared with EUR 380 per capita in the US ⁽⁷⁾.

2.11. Biomedical engineering is expected to be the fastest-growing job market in the United States during the next few years. According to the US Bureau of Labor Statistics (BLS), employment of biomedical engineers is projected to grow by 27 % between 2012 and 2022 ⁽⁸⁾.

2.12. In 2012 and 2013 the profession of biomedical engineer came first in the *Best Jobs in America* rankings ⁽⁹⁾.

2.13. In Europe, the sector directly employs around 575 000 people, many of them in highly skilled, high-value innovative jobs. There are almost 25 000 medical technology companies, of which 95 % are SMEs also dedicated to investing in research and development. The size of the market is currently estimated at roughly EUR 100 billion. Based on manufacturer prices, Europe's medical technology market is estimated at around 30 % of the world market. It is the second largest medical technology market after the US (around 40 % of the global market) ⁽¹⁰⁾.

⁽⁵⁾ Prof. Ștefan N. Constantinescu, Head of Signal Transduction & Molecular Haematology Unit. Member of Ludwig Institute for Cancer Research Ltd, de Duve Institute, Université Catholique de Louvain. (EESC hearing).

⁽⁶⁾ OECD Health Statistics 2014.

⁽⁷⁾ The European Medical Technology Industry in Figures.. MedTech Europe 2013.

⁽⁸⁾ <http://www.bls.gov/ooh/architecture-and-engineering/biomedical-engineers.htm>

⁽⁹⁾ <http://money.cnn.com/pf/best-jobs/2013/snapshots/1.html>

⁽¹⁰⁾ See footnote 7.

2.14. The European Commission is actively revising the legislation and technological requirements for devices and diagnostics and is involved in webstreaming of knowledge and skills.

2.15. The medical technology industry contributes significantly to the European economy and to competitiveness by providing large numbers of high-quality jobs, attracting substantial inward investment and creating innovation hubs. This sector offers huge global market potential for European industry, potential that needs to be tapped.

2.16. A very important role is played by nanotechnologies⁽¹¹⁾. We can now have innovative nano and biomaterials approaches for:

- Cancer
- Atherosclerosis
- Alzheimer's disease
- Diabetes
- Arthritis
- Ophthalmology
- Impairments
- Infectious and inflammatory diseases.

The current situation in the EU: 700+ nanomed and biomaterials companies in the EU: EUR 650 Mio invested in FP7⁽¹²⁾.

2.17. A very good example of the cooperation indispensable in this area is to be found in Flanders, Belgium, and is entitled 'MedTech Flanders'⁽¹³⁾. It comprehensively addresses all the needs to be required to move forward with the implementation of biomedical innovation — from trans-sectorial cooperation, to process optimisation, efficient use of human resources, financial aspects, and so on.

It helps existing MedTech Companies with:

- internal networking and knowledge-sharing;
- external visibility;
- equipment sharing and infrastructure;
- regulatory and Quality Affairs (QARA);
- human resources & recruitment;
- reimbursement;
- access to capital;
- business coaching;
- development of new companies/activities;
- merging clinicians, technicians and entrepreneurs;
- bringing technology and innovation to the bed side;
- reinforcing the general eco-system;
- better support for clinical trials;

⁽¹¹⁾ See EESC opinion on 'Nanoscience and nanotechnology' — 'Action Plan 2005-2009' (OJ C 185, 8.8.2006, p. 1).

⁽¹²⁾ Nicolas Gouze, General Secretary of ETP Nanomedicine (EESC hearing).

⁽¹³⁾ Prof. Pascal Verdonck NCBME, Senior full professor 'biomedical engineering', Ghent University; Director of Institute of Maria Middelares', Ghent (EESC hearing).

- systems for data collection;
- more efficient and (cost) effective healthcare.

3. Comments

3.1. The opportunities arising from increasingly personalised treatment and the sophisticated design of tailor-made drugs, devices, treatment, software, etc. are leading to new opportunities for European industries and SMEs. Furthermore, the enormous and still rapidly growing sector of general care for the elderly, disabled, and chronically ill, especially care at home, makes ambient assisted living an important issue to be considered, as this improves quality of life and safety at home, especially for people who cannot afford to be in care facilities. New technologies should improve health and safety at work and give staff more time for personal assistance (warm hands) to children, older people, disabled people and the chronically ill.

3.2. On 2 April 2014, the European Parliament adopted a legislative resolution on the European Commission's proposal for a regulation on medical devices. One of these measures that is particularly important is the involvement of the European Medicines Agency (EMA) in medical device regulation, namely in the qualification and monitoring of notified bodies (NBs); another concerns enhancing the roles of other bodies, including the new Medical Devices Coordination Group (MDCG), formed of representatives of the relevant Member State authorities, and the Assessment Committee for Medical Devices (ACMD), a scientific expert group which assists the MDCG. The European Parliament resolution would introduce enhanced competence requirements for NBs as well as 'special notified bodies' (SNBs) for specific categories of device.

3.3. The Innovative Medicines Initiative (IMI), launched in 2008, is Europe's largest public-private initiative. Its objective is to speed up the development of better and safer medicines for patients by supporting collaborative research projects and building networks of industrial and academic experts, so as to boost pharmaceutical innovation in Europe.

3.4. Information and Communication Technologies (ICT) applied to health and healthcare systems can increase their efficiency, improve quality of life and unlock innovation in health markets. The new eHealth Action Plan aims to address and remove existing barriers to the development of a fully mature and interoperable eHealth system in Europe, in line with the objectives of the Europe 2020 strategy and the Digital Agenda for Europe. Article 14 of the *Directive on the application of patients' rights in cross-border healthcare*, which establishes the eHealth network, represents a further step towards formal cooperation on eHealth between the Member States.

3.5. In this context, particular emphasis should be given to ePrescription. Greece has showcased best practices in electronic prescribing, proving that eHealth is not a luxury but a necessity. A first draft of the EU's ePrescription guidelines, which were supposed to have been adopted in November 2014, is intended to facilitate the interoperability of electronic prescriptions across borders, so that electronic prescriptions can be processed easily in any European Union country.

3.6. Under the Future internet Challenge eHealth (FICHe), a collaborative coordination and support project co-funded by the European Commission, funding is available to European eHealth small and medium-sized enterprises (SMEs) and start-ups, which wish to develop innovative applications in the eHealth domain using FIWARE technology.

3.7. Advanced medicine should:

- be smart everywhere, guaranteeing mobility even for people with serious diseases;
- shift from re-active curing to preventive strategies;
- change from blockbusters to personalised approaches;
- increase patients' empowerment and participation;
- improve mechanisms to protect data.

3.8. Increasingly innovative devices, materials and processes as well as rapid change in areas such as biotechnology call for flexible legislation without the additional layers of bureaucracy that delay patient access to innovative technologies. In this case, the use of delegated acts seems to be appropriate if they concern technical requirements.

4. Challenges and opportunities

4.1. According to the International Federation for Medical and Biological Engineering (IFMBE), there are challenges and opportunities for biomedical engineering in the following areas:

- ICT in medicine and healthcare;
- minimally invasive surgery;
- biomedical sensors;
- diagnostics;
- medical imaging and visualisation of data;
- intelligent materials;
- cellular and stem-cell engineering;
- nanotechnology;
- modelling and simulation of physiological systems and the human body as a whole.

4.2. Thanks to increasingly efficient use of medical devices and to the joined-up use of medical devices and medicines (i. e. electrochemotherapy), cancer is now considered to be a chronic disease, with life expectancy and quality of life virtually trebling in the last 10 years.

4.3. Innovative medical technology delivers extremely important benefits to Europe's citizens by helping them to live healthier lives for a longer time. Many people who were chronically ill, disabled, or suffering chronic pain can now lead normal or close-to-normal lives. Here are some examples:

- The use of coronary stents in the treatment of cardiovascular disease has reduced the number of people dying from heart attacks or suffering heart failure.
- Patients suffering from diabetes now have access to very accurate blood glucose monitoring technologies, which reduces the risk of diabetes complications such as blindness and peripheral nerve damage.
- The use of minimally invasive surgical techniques to treat aneurysms allows a recovery time of around four weeks, compared with over a year for older procedures.

4.4. The innovative field of 3D printing has a key role to play in the future empowerment of doctors, researchers and medical device manufacturers. 3D-printing technologies allow customisation in a wide variety of applications in the medical field, producing devices that are perfectly suited to a particular individual. There are already a number of application areas for 3D printing using specialised materials that must meet rigid and stringent bio-compatibility standards (bio-compatible, drug-contact materials, etc.). In addition, legislation is envisaged covering the treatment of products made with 3D printers and defining the applications of these products in the medical field.

5. Biomedical engineering education and development in Europe

5.1. The conclusions of the European Council of 20—21 March 2014 urged the Commission and the Member States 'to address shortages in the area of science, technology, engineering and mathematics (STEM skills) as a matter of priority, with increased involvement of industry'.

- 5.2. The EESC calls on the Commission to ensure adequate follow-up to this request from the European Council, at both European, national and local level.
- 5.3. The future EU 2020 strategy should include measures to promote the quality and availability of STEM skills in both the private and public sector.
- 5.4. Biomedical engineering in medical and care services may play a major role in responding to general societal challenges like demographic change, shrinking of the tax base, and growth in demand for healthcare facilities.
- 5.5. In this respect the World Health Organization recognises that more biomedical engineering professionals are required to design, evaluate, regulate, maintain and manage medical devices, and train on their safe use in health systems around the world ⁽¹⁴⁾.
- 5.6. Member States should adopt long-term, coherent healthcare programmes and action plans to develop innovative research, new technologies and high-quality education in biomedical and other relevant areas of engineering.
- 5.7. The EU should promote a single market for the European medical technology industry, among other things through adequate standardisation in the field of biomedical engineering in combination with the care services industry, ICT and health informatics. This could offer tremendous advantages for European industry and enhance the quality of medical care.
- 5.8. Special attention should be paid to SMEs, for instance in terms of their access to financing for start-ups, the promotion of innovative cooperation between SMEs and relevant research institutions, and steps to facilitate commercialisation of their inventions.
- 5.9. Biomedical engineering is the fastest growing engineering discipline and is today considered one of the most promising career paths. It bridges the medical/biomedical and engineering disciplines, enhancing and increasing the efficiency of healthcare overall. Biomedical engineers design and build innovative devices such as artificial limbs and organs, new-generation imaging machines and advanced prosthetics; and they improve processes for genetic testing and for making and administering drugs.
- 5.10. While the US has progressed in the development of biomedical engineering education and training opportunities, Europe, despite a large biotechnology medical and biological engineering sector and excellent education systems, has had difficulties in creating uniform standards because of persisting national jurisdictional barriers. The BIOMEDEA initiative launched in 2004 aims to develop and establish educational and professional standards in this field.
- 5.11. Biomedical Engineering should be recognised in the EU Professional Qualifications Directive ⁽¹⁵⁾.
- 5.12. European and national strategies in health and care services and university research policies should complement one another to ensure a broad base of knowledge and experience from which it is easy to collaborate with industry (in particular SMEs), branch off start-ups and set up international collaborations. Calls should aim at integrating new emerging technologies and medical and biological science, so as to make Europe a global leader in medical technology (tackling real medical challenges).
- 5.13. Under the CRH-BME Tempus project, 150 universities across Europe are offering a total of 309 biomedical engineering programmes across BSc, MSc and PhD courses. The CEMACUBE European Masters programme, set up under the European Commission's 2009-13 Erasmus Mundus Programme, aims to foster cooperation between higher education institutions and academic staff in Europe and third countries. Erasmus Mundus is no longer running as a course programme, which means that no more CEMACUBE scholarships are available.

Brussels, 23 April 2015.

The President
of the European Economic and Social Committee
Henri MALOSSE

⁽¹⁴⁾ WHO, last visited 23 March 2015; http://www.who.int/medical_devices/support/en/

⁽¹⁵⁾ André C Linnenbank, Secretary-General EAMBES (EESC hearing).