Opinion of the European Economic and Social Committee on 'Industrial change in the health sector'

(own-initiative opinion)

(2018/C 227/02)

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1. **Conclusions**

1.1. The medical technological industry — focus of the opinion — plays a major role in the current transformation of the health sector to the benefit of patients and a value-based health care in Europe.

1.2. A major issue is highly personalised health care that ensures equal and better access and quality. Technology and large sources of anonymous data will greatly facilitate new treatments and operations as well benefit all phases of prevention and recovery. Recovery increasingly takes place outside hospitals, using eHealth technology.

1.3. Subsidiarity is cautiously guarded in health care systems as services of general interest. The medical sector and its organisation are very decentralised and fragmented. National and regional barriers must be reduced to optimise outcomes of new technologies and achieve better efficiency and effectiveness in line with the publicly defined objectives of health care systems.

1.4. The ongoing interaction between the great variety of relevant stakeholders — national ministries, patient organisations, medical staff and other personnel in health care, hospitals, insurance companies and supervision — creates a complex environment for industrial actors, notably SMEs.

1.5. The industrial transformation process is also considered to take due account of the common values and principles that underpin Europe's health systems, as laid down by the Council in 2006 ([1]), as well as confirmed in recent commitments in the EU social pillar and the agreed Sustainable Development Goals ([2]).

1.6. Industry needs the European scale as a basis for a reliable domestic market as well as to build sufficient international resilience. The EU is critically important for the creation of a better playing field as well as for guiding and monitoring transformation processes.

([1]) See EPSCO Council Conclusions (2006/C 146/01) and its Annex, 2 June 2006 on the impact of European values.
([2]) See notably the goals 3, 5, 9, and 10.

1.7. Key stakeholders and Member States should develop optimal approaches and commitments regarding access to and quality of health and care, affordability, and prevention. In the same context special approaches, also concerning nursing, are required to meet the needs of vulnerable, notably elderly people. As important are optimal approaches towards new technologies and innovation, integrated care models, and alliances, as well as (cross-border) networks and (large-scale) PPPs. Proper implementation of EU rules and guidelines should be ensured. Each of these issues requires the Commission services to play an active and stimulating role.

Recommendations

1.8. The European institutions should foster economic performance, innovation, digitalisation and effective public procurement, while facilitating cross-border trade in medical devices and industrial products.

1.9. An EU industrial policy must build upon shared national and EU competences in the framework of Article 168 TFEU. In the same vein, EU innovation policies should be supportive. EU funding — Horizon 2020- and other — must be duly coordinated and dovetailed with national programmes.

1.10. The industry will benefit massively from the Digital Single Market strategy. Free flow of (big) data across the Union should be promoted, respecting patient privacy and security.

1.11. Public procurement has a major role in launching projects with advanced technologies. The Commission should ensure effective public procurement across the Union in line with Directive 2014/12/EC.

1.12. Within the broader context of national approaches there are many region based initiatives. The Commission should promote exchange of successful experiences. Bilateral contacts between public and private health authorities must be encouraged.

1.13. The European Semester and CSRs ([3]) should also examine the effect of technological change on the transformation of health systems.

1.14. The Commission must seek efficient internal coordination. It should foster dialogues and platforms between universities, local authorities, the social partners and the medical technological industry. These can be exemplary for close cooperation between public actors such as national health, finance and industry ministries, and the private sector.

1.15. The human factor is paramount. The transition to new health and care requires an open mind and new forms of professionalism in industry at all levels, as well as a redesign of health and care related work. The European social dialogue in health and social services that is in place since 2006 should be reinforced in view of adequate education and training programmes as well as to upgrade the quality of working conditions and work places.

2. **The current picture**

2.1. In various opinions, the EESC has discussed the latest developments in the health sector ([4]). This opinion focuses specifically on the current deep transformation in the medical technology industry.

2.2. The European technological medical sector alone employs more than 575 000 people, working in approximately 26 000 companies. The industrial landscape is dominated by SMEs interacting with big companies.

([3]) Country Specific Recommendations.

([4]) OJ C 181, 21.6.2012, p. 160, OJ C 242, 23.7.2015, p. 48, SOC/560 — Sustainable social security and social protection systems in the digital era (not yet published in OJ), OJ C 133, 9.5.2013, p. 52, OJ C 434, 15.12.2017, p. 1.

2.3. The sector is estimated at roughly EUR 100 billion. The positive trade balance of EUR 14,1 billion in 2015 was double that of 2006 and went substantially beyond the American trade surplus of EUR 5 billion. The sector has excellent future prospects.

2.4. Research is driven by both continuous step-innovation and breakthrough and disruptive innovation in business, but often also as spin-offs from existing structures such as university hospitals. The number of patents shows the added value through innovation. In 2015, there were 12 474 patent applications in the area of medical technology. This number amounts to roughly 17 % more than in digital communication and computer communication, and nearly 55 % more than in pharmaceuticals and biotechnology ([5]).

2.5. In 2015, health and long-term care accounted for 8,7 % of GDP in the EU and for 15 % of total government expenditure. This could rise to 12,6 % of GDP by 2060 due to more costly treatments, ageing populations and the sharp rise in chronic diseases and co-morbidities ([6]). Due to financial constraints, healthcare delivery needs increasingly to cope with budget pressure. This may lead to short-term budget cuts that have a negative effect on R & D expenditure.

2.6. Co-creation and cooperation between large corporations and SMEs is the norm. Corporations focus on developing capital-intensive hardware and software platforms, while SMEs focus on specific platforms for specific purposes.

2.7. The differences between countries are significant. Health systems and financial structures, as well as the state of technology, including the absorption of innovative solutions and prevailing medical practices, also vary greatly from country to country.

2.8. Besides opportunities, the medical technology industry faces major challenges. It is an industrial sector in its own right due to the predominance of public actors, a wide range of stakeholders, the impact of European values ([7]) and the need for sustainable public finance, as well as due to cautiously guarded subsidiarity principle and often decentralised, usually regionally-based, ecosystems.

2.9. Regions are a fertile basis for cooperation. A lack of bundling initiatives and regional fragmentation, however, often block innovative SMEs, as their capacity to attract equity investment is directly related to their ability to develop larger markets for digital health solutions.

2.10. In contrast to the United States, where a large part of healthcare is organised through private insurance systems, health care in Europe is primarily publicly funded.

2.11. Progress in medical technology is driven by close interaction between all stakeholders. The ecosystem is drastically changing, with new players driving the digital transformation. The sector has to strike a delicate balance between market forces and public interest that requires affordable healthcare for all.

2.12. It has to operate in an environment of industry, doctors, hospitals, empowered patients and patient organisations, and insurance companies (including national statutory/mandatory social security systems); in other words, many interacting stakeholders are functioning in a complex system.

2.13. Technology and innovation are embedded in this specific ecosystem. Innovation is no longer mainly driven by the supply side. Current practices show a shift towards the demand side, which is generally not very keen to adopt new approaches. The final outcome is usually the fruit of intense coordination between all stakeholders at national and often regional level.

([5]) The European Medical Technological Industry in figures, 2015.
([6]) European Commission, 2017.
([7]) See note 1.

2.14. Industry focuses on specific solutions and the renewal of any element in the industrial value chain. Each medical specialty has its own features. In parallel, there are increasingly integrated care solutions.

2.15. The system as it functions is continuously tested. It is far from easy for industry to comply with all requirements while regulatory obligations sometimes overlap.

3. **EU industrial policy**

3.1. The EESC welcomes the recent EU focus on more productive output in health through more innovation, greater (cost-) efficiency, better access and increased e-skills ([8]). The digital single market strategy opens new windows of opportunity as well as challenges.

3.2. EU industrial policy can build upon shared national and EU competences in the framework of Article 168 TFEU ([9]). Stepping up cooperation with the WHO and the OECD goes in parallel. EU and national authorities should actively fight counter-productive fragmentation. Objective measurements are desirable.

3.3. Industrial performance as well as interaction between industry and national and regional stakeholders must be fostered. EU funding mechanisms and national funding should be complementary. European, national and regional objectives should be brought under the same umbrella.

3.4. A range of directives and guidelines in the health sector also concerns industry: on health and safety ([10]), on patient's rights ([11]), on privacy, and on intellectual property rights. Notably FP7/Horizon 2020 and Cohesion Policy Funding, are co-funding medical devices related projects. Horizon 2020 has, for academic and medical technologies, especially benefitted the pharmaceutical industry. Since 2015, EIT has been very active in financing regional initiatives ([12]).

3.5. An EU industrial policy is critical given the financial support and technological achievements in competing jurisdictions. In China, the *China 2025* strategy amounts to favouring domestic brands and to incentives for hospitals to privilege Chinese industry and to discourage foreign investment. This may hit European companies hard. Given existing and increasing protectionism in the US, one can hardly speak of an Atlantic level playing field. In the US, a digital revolution is also on its way ([13]). Businesses from the US have easy access to the European market. Google is a strong new competitor. EU trade negotiations must secure up-to-date European production in providing universal health care.

3.6. The optimisation of data increases opportunities to all Europe-based companies ([14]). Electronic Health Record (EHR) systems are very costly. The fragmentation of and cross-border barriers to health data hamper interoperability efforts and European SMEs. Future personalised medical solutions — better prevention, more accurate diagnosis, better treatment — will benefit largely from pooling data and resources across the EU. This pooling is still relatively modest as compared to the US and China.

([8]) See EPSCO Council Conclusions (2006/C 146/01) and its Annex, 2 June 2006 on the impact of European values.
([9]) Article 168 in Title XIV TFEU: Public Health.
([10]) Recently, the Council again adopted two regulations with a heavy impact on industry: one on new devices and one on in vitro diagnostics.
([11]) See in this context art. 35 of the Charter of Fundamental Rights, doc. 2012/C 326/02, and the European Charter of Patients' Rights, 2002.
([12]) The EIT KIC Health (European Institute of Technology and Innovation — Knowledge and Innovation Community) was established on 9 December 2014.
([13]) See study Goldman Sachs, 1917: *A digital healthcare revolution is coming — and it could save America $300 billion.*
([14]) See Commission Communication *Building a European Data Economy,* March 2011 and the EESC's reaction TEN/630.

3.7. PPPs of stakeholders in the public and private sector need to be carefully assessed and monitored regarding their capability to create innovative and sustainable solutions, industrial objectives, and beneficial interaction and exchanges.

4. **Innovation and the need for sustainable long-term solutions**

4.1. Presently, technological investment in the healthcare system is limited to 2-3 % of total healthcare costs. The range of innovations applies in detail to every single medical specialty ([15]), greatly affecting the future of the medical profession as well as the organisation of hospitals and the health sector in general. New business models are being put in place across the Union.

4.2. Financial pressure may lead to cheaper short-term solutions and thus to less innovation. Moreover, incentives in various Member States do not contribute properly to innovation but may lead to unmet medical needs or reduced utility for patients and, ultimately, to more costly treatments. Bilateral exchanges and sharing initiatives at European scale are desirable.

4.3. Productive regional cooperation and *living labs* in the sector should be encouraged. The EIT fosters cooperation by promoting catalyst developments and synergies, amongst others via *hubs*, as well as by promoting dialogues, platforms and inter-linkages for individual projects.

4.4. Digital innovation, notably concerning mobile health applications, can help to address risk factors that are associated with chronic diseases. Mobile health and remote monitoring support prevention and may also reduce the need for burdensome treatments later on.

4.5. R & D and innovation are not self-propelling forces. On the demand side — which is almost exclusively the public sector — there is often risk aversion and a tendency to opt for the cheapest solution.

4.6. Sometimes distrust of public authorities has to be overcome. Medical staff may slow down innovations that may lead to a change of working methods, for instance in surgery, or to completely new treatments, for instance those involving robotics. Financial provisions for medical specialists may also hamper willingness to innovate. Insurance companies are not always cooperative either. In short, a natural openness towards innovation will often require a cultural shift in order to derive the full benefits.

4.7. An overview of the various beneficial innovations that are fostering quality of life, disease prevention, improved and extended life expectancy as well as better cost/price ratios, would be helpful.

4.8. This will also be in line with the concept of 'money for value'. Health and care has been — and potentially still is — the fastest growing sector in national budgets. A common awareness of the need for innovation and long-term solutions for patients should prevail among finance ministries, health ministries and stakeholders.

4.9. From the same perspective, the European Funds and, where appropriate, in combination with national funds, are indispensable.

5. **Public procurement**

5.1. An estimated 70 % of global medtech sales go through a public procurement process, and 70 % of the decisions in those cases are determined on the basis of price, with each of these figures on the increase. This usually leads to less competitiveness and less innovation/new technologies, resulting in higher costs and reduced added value for patients ([16]).

([15]) See, inter alia, the Strategic Research Agenda under Horizon 2020, COCIR, September 2016.
([16]) *Procurement, The Unexpected Driver of Value Based Health Care*, Boston Consulting Group — MedTech Europe, 2015.

5.2. Rising costs should be an incentive for hospitals and health systems to move away from purchasing medical products on the basis of up-front purchase costs ([17]). Important aspects are:

— Significant savings if short-term gains in purchasing are replaced by well-calculated long-term advantages

— Innovative solutions, promoting quality in combination with total lifecycle costs

— Sufficient specialised knowledge among purchasers that is often lacking

— Transparent and non-discriminatory negotiations between supply and demand.

5.3. Competent purchasers, focusing on the latest and proven innovations, should be considered essential to the output. To a certain extent, the purchaser may be seen as the link between the interests of the patient and the supplier, saving costs and fostering output.

5.4. Tenders must be considered from a holistic point of view that takes into consideration the quality and costs of products and services over their whole life-cycle. This will equally support the need for integrated care, supported by the Integrated Care Alliance ([18]).

5.5. All stakeholders share responsibility for identifying the needs of users and partners in the tendering process. This is a difficult process due to the multi-faceted challenges associated with calculating costs and assessing quality across the broad range of areas in the medical sector. It requires the right mind-set among all stakeholders. Sharing best practices in Europe and open transnational discussions and exchanges at EU level will be a great help.

6. **Digitalisation**

6.1. Technological shifts and the disruptive, transversal effects of digitalisation require deep commitment and participation from all stakeholders in the health sector.

6.2. eHealth will allow professionals to interact remotely with patients and other colleagues. It helps spread specialised knowledge and facilitate research. It creates a wide variety of new solutions and is undoubtedly a factor for growth. It will also alleviate the burden on health budgets. mHealth is improving health care at home. It plays a critical role in promoting the mobility of patients, while data, patient privacy and security must be ensured.

6.3. The Commission considers that 'a big gap still remains between the potential of digital transformation and the reality of health and care systems today' ([19]). The obstacles are manifold: national legislation, financing and payment systems, traditional approaches across the medical and public sector, market fragmentation and a lack of scaled-ups. Industry also has an interest in looking for the right implementation of transformation to avoid unsatisfactory outcomes and, possibly, a greater workload.

6.4. On the other hand, as health is a major sector (around 10 % of EU GDP), the prospects of massive digitalisation open big opportunities for further expansion ([20]). Awareness of the impact of digitalisation, including artificial intelligence, is growing fast ([21]). The Commission recently adopted a Communication that addresses three priorities in the digital single market strategy for the health and care sector:

— Secure access by the public to electronic health records and the possibility of cross-border sharing, as well as the use of e-prescriptions

([17]) The health sector is by no means the only sector that suffers from such practices. The *lowest price* syndrome prevails in most public procurement across Europe. It is one main reason for European legislation, see notably the Public Procurement Directive of 2014.
([18]) See, amongst others, the *European Blue Print*, DG CNECT (chapter 6, below) and www.integratedcarealliance.org
([19]) See European Industry: Working Group 2 — Digital Industrial Platforms, chapter 5, Overview of the Strategy in 'Digital Transformation of Health and Care'.
([20]) See Working Group 2, p. 31.
([21]) See, inter alia, *Blueprint on Digital Transformation of Health and Care for the Ageing Society, a Strategic Vision developed by Stakeholders*, Brussels, 5-8 December 2016.

— Support for data infrastructure for advanced research, disease prevention and personalised health and care in key areas

— Facilitation of feedback and interaction between patients and healthcare providers, supporting prevention and citizen empowerment, as well as quality and patient-centred care, focusing on chronic diseases and better outcomes of healthcare systems.

6.5. The *Blueprint* states that, unless the EU aligns effective innovation and economic and industrial policies with health and social care policies, as well as with users' and patients' needs, 'our social and economic models as well as the quality of life of our population are at risk. This is a crucial point we need to address' ([22]). The OECD concludes that governments play a crucial role as a source of leadership in enabling the effective use of ICT in changing and redesigning health systems ([23]). The OECD notes, however, that fragmentation and the rapidly evolving nature of technological solutions, combined with a lack of industry-wide standards and compliance with existing rules on ICT systems, may lead to a high risk of failure and poor returns ([24]).

6.6. A broad spectrum of successful eHealth initiatives already exists. However, there are substantial differences between countries and regions. An overarching strategy of interaction and synergy was recently launched in the Digitising European Industry (DEI) project as well as 'a new model for linking up different EU initiatives, with clear industry commitments as well as support from Member States and regional strategies' ([25]).

6.7. Following the example of *Industry 4.0*, the Commission has now launched *Health 4.0*. EU programmes are underway. Like-mindedness among all of the DGs concerned is needed in order to achieve synergies. Technology platforms that operate in parallel with national and regional initiatives as well as (cross-border) networking must be encouraged. The recently established taskforce should foster similar developments ([26]).

6.8. A number of EU pilots and initiatives are not fully completed, while new initiatives have been started. A more sustainable method would be to have permanent mechanisms in place to support industry and innovation, including implementation.

6.9. Big data has great potential to further radical shifts in medical treatment. It is important that electronic health records are securely managed and protected in line with healthcare data management protocols complying with government regulations ([27]). Effective CPD strategies ([28]) are important, especially in data management and privacy standards for patients, cloud environments and security investments in big data storage.

6.10. Statistics prove that the healthcare sector is particularly vulnerable to cyber attacks. Consequently, cyber security must also be a priority in new industrial applications.

6.11. Big data supports personalisation, including in the relationship between producers and patients. It affects the following areas:

— A shift from healthcare to home care

— A shift from generic solutions to personalised treatment

— A shift from cure to prevention

— The removal of restrictions in the case of illness or disability

([22]) *Blueprint*, p. 6.
([23]) *Improving Health Sector Efficiency, the role of Information and Communication technologies*, OECD 2010.
([24]) Ibid. p. 16.
([25]) Working Group 2, p. 35.
([26]) Taskforce to take health and digital policies further, 27 February 2017.
([27]) See also the 2012 framework for data protection.
([28]) Continuing Professional Development Strategies.

6.12. Digitalisation and Big Data not only favour the proliferation of individual sensors and devices, they also play a key role in new diagnostics, research and prevention as well as in supporting patient-empowerment and self-management, while opening up optimal solutions for integrated care. The exchange of patients' data will be critical for interoperability.

6.13. European best practices and peer pressure as well as objective assessments and pilots will be helpful, provided these pilots are carried out in full.

7. **Social impact and skills**

7.1. The transformation in industry has a social impact both in the medical industry itself and in the health sector at large. As in other industrial sectors, the change of business models due to digitalisation requires an adjustment of working conditions and labour market mechanisms as well the involvement of the social partners at various levels.

7.2. Technology and innovation usually have a strong effect on the situation of workers in the health sector itself. In addition to and together with more closely connected stakeholders such as hospitals and clinics, the industry can help to prepare the workforce for changing environments and treatments.

7.3. Special approaches and tools are required to meet the needs of vulnerable, notably elderly people (retirement homes) who should benefit from specific personalised kinds of support and assistance. Professional nursing needs focused training in applying new technologies to this category of patients.

7.4. Health and care are among the biggest job providers in the EU. A predicted shortage of up to 2 million health workers and 20 million care workers in the EU by 2025 presents a challenge for a sustainable future development of the sector as a whole ([29]).

7.5. An optimised health and care system will significantly benefit from the input and commitment of a highly skilled and motivated care system. Often health and care jobs are precarious, poorly paid and quite burdensome. The mismatch between needs and required work (quality) calls for a redesign of health- and care-related work and organisation.

7.6. ICT and smart organisations can help create more attractive and productive working conditions and better work-places. Perceived risks and problems as well as all kinds of questions due to new technologies should be addressed by comprehensive information and consultation in line with the rights of health care personnel at various levels.

7.7. New skills, adjusted working methods and patient-empowerment have a big impact. These processes can only be successfully accomplished by the commitment of all parties concerned. These should result from national, sectoral or enterprise-based agreements and/or solutions that prepare employees and health organisations properly for upcoming changes. Since 2006, an EU sectoral social dialogue committee for the hospital/health care sector has been in place.

7.8. Education and practice, as well as ongoing training, are crucial. Common European education and training modules are desirable. Exchanges on awareness building and best practices in Europe on these issues between the parties concerned should be promoted. Education and training were covered in a Joint Declaration of the social partners in 2016 ([30]).

7.9. EU-wide best practices in health and care concerning system developments and evaluation of smart organisations can also be helpful in promoting promising methods of worker participation.

([29]) *Blueprint*, p. 19.

([30]) See Joint Declaration by HOSPEM and EPSU — social partners — on Continuing Professional Development and Life Long Learning for All Health Workers in the EU, November 2016. See for further information on the need for investment in the workforce of the health sector the Joint UN/ILO/WHO/OECD report *Working for health and growth: investing in the health workforce*.

7.10. The need to have an open mind to new ICT-enabled solutions requires all health and care professionals to be digitally literate and up-to-date with the latest technologies. In addition to the skills of the full range of professionals, patient-empowerment also requires the right mind-set and corresponding competences.

7.11. In parallel to healthcare professionals, there is a need to build medical knowledge in the IT business with a view to optimising the use of IT tools in health and care.

7.12. Employment in informal and social care must also be up-to-date. Informal care is increasing disproportionately, as is patient-empowerment. Both can greatly improve the mobility of the ageing generation for disabled and healthy elderly people alike. The term 'silver economy' is self-explanatory.

Brussels, 14 February 2018.

The President
of the European Economic and Social Committee
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