

Analysis of the External Environment – European Patients’ Forum 2017



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1. Introduction and foreword from the authors

This study has been commissioned by the European Patients’ Forum (EPF) and prepared by Stefan Gijssels and Anna Dé.

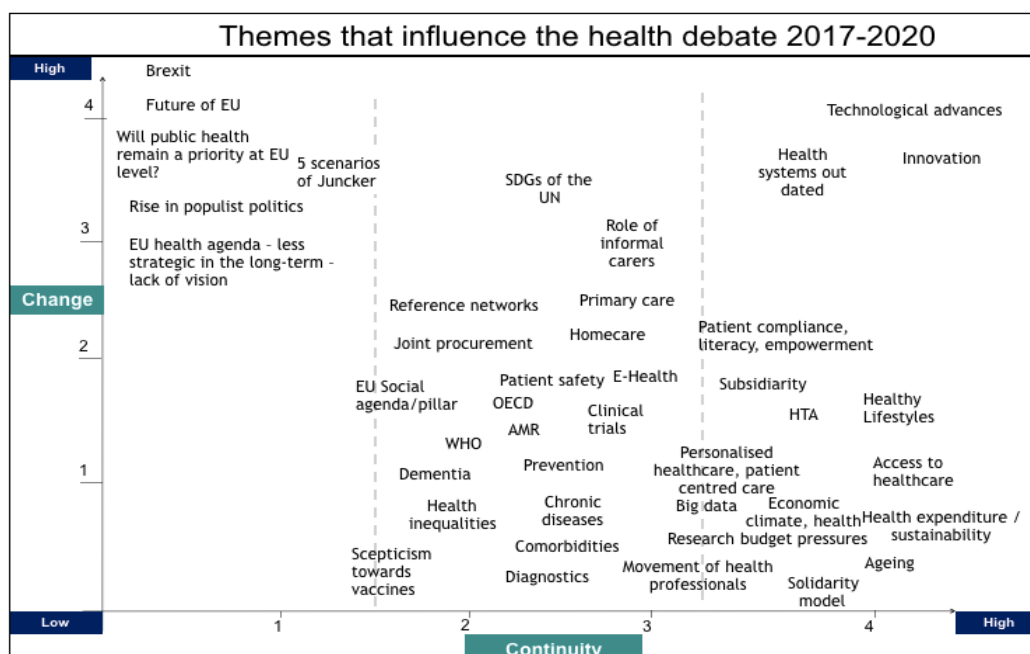
The following analysis of the external environment is based on desk research and open discussions with ten European stakeholders and opinion-leaders from various backgrounds, including patient organisations, consultants, representatives from the European Commission, pharmaceutical industry, pharmacists, payers and health economists. We asked them what major changes have happened in the past years and are expected to happen in the coming years, as well as which major trends are expected to continue.

We articulated these changes around the major topics of politics, economy, society and technology, even if the distinction between some of them is slightly artificial and sometimes difficult to make. Clearly, these areas are not mutually exclusive and there are some overlapping elements. Based on the various stakeholders’ insights, we carried out additional desk research.

We tried to base our analysis as much as possible on EU figures, and when these were not available we based ourselves on global figures or data from the Organisation for Economic Co-operation and Development (OECD).

The objective of the analysis is to identify the external context for the European Patients’ Forum to assess how its existing Strategic Plan 2014-2020 should be altered or maintained in the coming years.

Our interviews with stakeholders identified the following areas as the highest priorities/highest importance (see grid below).



In terms of environmental changes, the most common topics mentioned were Brexit, the “future of Europe”, the five scenarios of Commission President Juncker, the rise of the populist agenda, and the potential changes in the role of the European Union (EU) regarding health.

The most important continuing trends mentioned by the stakeholders include: issues around the sustainability of healthcare systems, the ageing population, access to healthcare and healthy lifestyles.

Some topics were mentioned as both continuing and changing: technological advances, innovation, and the fact that current healthcare systems often lag behind technological evolution.

2. Politics

The major changes on the political front are the planned departure of the UK from the EU (Brexit) and the election of a new administration in the United States. There is a clear rise in nationalism, populism and protectionism across the European region, with strong political debates and the polarisation of opinions in Germany, France, Denmark, the Netherlands, Austria and Sweden, coupled with the strong anti-European stance of countries such as Hungary and Poland.

The build-up of troops around the European Union’s borders, the crisis in Ukraine and the increased tension between the global forces of the United States, Russia and China are expected to double defence expenses in the coming decades¹. This may have implications on the allocation of money in research, with a stronger emphasis to be put on engineering and software development, to the detriment of health research.

The lack of trust in authorities and institutions is visible in the 2016 Eurobarometer survey², which shows that only 36% of the Europeans trust the European Union, and only 31% trust their national government. Even if these are not the lowest figures of the past few years, they do not alter the downward trend of the past decade. This lack of trust is also visible in healthcare systems: globally, trust in the healthcare sector is decreasing, with a higher trust among the “informed public” versus the “mass population”, according to the Edelman Trust Barometer 2016. The difference is even more prominent among the European countries participating in the survey. Within the healthcare sector, hospitals are the most trusted (66%), followed by biotech (60%), over-the-counter medicines (55%), healthcare insurance (54%) and pharmaceuticals (53%). In Europe, trust is increasing in hospitals, biotechnology and health insurance, while trust in pharmaceuticals is declining in almost every country, with the exception of Spain³.

¹ UK Ministry of Defense: Strategic Trends Programme - Global Strategic Trends - Out to 2045

² Eurobarometer 2016

³ Edelman Trust Barometer 2017

2.1 BREXIT

When it comes to Brexit, *“it is feasible that the broad framework for a free trade agreement will have been drawn up by the deadline in early 2019, leaving the precise terms of the deal to be phased in gradually. If negotiations fail and no extension is agreed, the UK would leave the EU without any agreement in place and revert to World Trade Organisation (WTO) trade rules. This would mean a rise in tariff barriers that would be damaging to both sides⁴”*.

Some commentators believe that Brexit will not have a significant impact on EU health policies. However, Brexit will have consequences on certain aspects of health. The European Medicines Agency (EMA) will thus have to move to continental Europe. Still, the most direct impact may be on the United Kingdom itself, where the National Health Service relies on a significant number of foreign healthcare professionals. Cross-border healthcare will be impacted, a UK-specific approval system for new medicines will need to be set up, and the possibility for the UK to benefit from EU research funding will disappear or be slimmed down.

In the Horizon 2020 research programme, an important share of the EU-funded projects involves UK researchers. The UK could continue to participate in the programme under the same conditions as Norway or Switzerland, but the impact of Brexit will be felt. Several healthcare organisations from the NHS itself, the NHS European Office, the Association of the British Pharmaceutical Industry (ABPI) to health societies and the Society of Social Medicine are trying to influence the shape of health matters for the UK post-Brexit.

Beyond health specifically, the departure of the UK will have an impact on the overall EU budget in the long-term. The impact that this might have on the EU budget on health is yet to be determined.

At the same time, the world’s largest research organisation, the US National Institute of Health, will face a budget cut of US\$1.8 billion in annual research grants.

2.2 FUTURE OF EUROPE

In March 2017, European Commission President Jean-Claude Juncker launched his White Paper for the Future of Europe, offering 5 scenarios to be debated at various levels in the Union. The scenarios are *“Carrying On, Nothing but the Single Market, Those Who Want More Do More, Doing Less More Efficiently, and Doing Much More Together⁵”*.

In the first scenario, the EU27 sticks to its course and focuses on implementing and upgrading its current reform agenda. This scenario implies that the current health-related agenda would also be pursued.

In the second scenario, the EU27 cannot agree to do more in many policy areas and focuses on

⁴ Economist Intelligence Unit, March 2017

⁵ European Commission - White Paper on the Future of Europe, 2017

deepening certain key aspects of the single market. There is no shared resolve to work more together in areas such as migration, security or defence. For healthcare, this could mean the continuation of a single market for products such as pharmaceuticals, although health services could be organised at the national level only. Cross-border healthcare could disappear and working in a healthcare job abroad will become more difficult. In this scenario, the role of the EU in fora such as the World Health Organisation (WHO) might also be affected.

In the third scenario, the EU27 proceeds as it does today but where certain Member States want to do more in common, one or several “coalitions of the willing” emerge to work together in specific policy areas. The areas mentioned for deepened cooperation are defence, fighting crime and terrorism and justice, as well as social standards and tax harmonisation. Health could be part of this, even if it is not likely at this stage.

In the fourth scenario, there is a consensus on the need to better tackle certain priorities together. The EU27 decides to focus its attention and limited resources on a reduced number of areas. *“Conversely, the EU27 stops acting or does less in domains where it is perceived as having more limited added value, or as being unable to deliver on promises. This includes areas such as regional development, public health, or parts of employment and social policy not directly related to the functioning of the single market”*. This is the only scenario in which health is explicitly mentioned, albeit in a negative way.

In scenario five there is *“consensus that neither the EU27 as it is, nor European countries on their own, are well-equipped enough to face the challenges of the day, Member States decide to share more power, resources and decision-making across the board”*. If that scenario is chosen, healthcare could be organised in a more European-wide mode, with stronger possibilities for “hard” law and funding with regard to health. This offers the opportunity to have a more ambitious vision on how to organise health and healthcare.

From a patient perspective, the fifth scenario is possibly the one which provides the best opportunities, as it offers a harmonised approach, more sharing of knowledge and systems insights, cross-border healthcare and a more unified research approach. In the European Commission’s top 10 priorities, health is currently not mentioned: scenario five may offer an opportunity for change.

It may also make healthcare systems more cost-effective. Already now, between 2016 and 2020, 79 organisations will work on a sustainable network to further collaboration in ‘health technology assessment’ (HTA), the discipline of health economics that evaluates the cost-effectiveness of new medical technology, such as pharmaceuticals and medical equipment. EUNetHTA, the European organisation of HTA agencies, has developed its own scenarios that could vary from a mutual information among national HTA agencies to a full cooperation by having a European assessment of new health technologies.

2.3 THE EU HEALTH AGENDA

There is increasing recognition that current European health systems are outdated, and ill-equipped to meet future challenges, but currently there is no consensus as to what kind of system is “best”. All

reforms address chronic disease management and prevention, and cost containment, while continuing to provide citizens with high-quality healthcare.

The focus of EU in health has always been predominantly on health promotion and primary prevention, with citizens and consumers as the main reference groups in this context rather than patients. This can be both an opportunity for patients with chronic and lifelong conditions (effective prevention can free resources for patient care) and a challenge (a focus on primary prevention may marginalise the needs of patients with chronic diseases). Recent initiatives including an attempt to align the Health Technology Assessment, the establishment of the Health Systems Performance Assessment (HSPA) expert group, the Commission Expert Group on Safe and Timely Access to Medicines for Patients ("STAMP") and the collaboration with OECD on quality indicators may point to a shift to more healthcare-orientated initiatives.

In November 2011, following a consultation, the European Commission adopted its Third Health Programme "**Health for Growth**" 2014-2020, funding projects over a 7-year period for a total amount of 449,9 million euro.

The most recently created output of this programme are the European Reference Networks (ERNs). The first ERNs were launched in March 2017, involving more than 900 highly-specialised healthcare units from over 300 hospitals in 26 Member States. 24 ERNs are now working on a range of thematic issues including bone disorders, childhood cancer and immunodeficiency.

The 2013 European Commission staff working document "**Investing in Health**", identified three priority areas to grow prosperity in the region: spending smarter, but not necessarily more; investing in people's health, particularly through health promotion programmes; and investing in health coverage as a way of reducing inequalities and tackling social exclusion.

In May 2017, the results from the mid-term review were published, based on a consultation with the stakeholders, who were largely supportive of the initiative⁶.

The European Commission identifies its key challenges for 2016-2020 as follows: EU action in the public health area is mainly linked to incentives and cooperation measures. It has an important supporting role to play, notably in providing guidance and tools to promote cooperation and in helping national systems to operate more effectively. EU action should therefore focus on the following challenges: achieving greater cost-effectiveness; competitiveness together with safety; tackling emerging global threats; evidence-based policy making; addressing the risk factors of chronic disease.

The European Commission also presented its Roadmap for evidence-based policy-making: the bi-annual publication '**Health At A Glance**', which presents the current health status in the Union and includes individual country health profiles, as well as a Commission Paper which will build on the findings of both reports, linking them to the broader EU agenda, emphasising cross-cutting policy

⁶ https://ec.europa.eu/health/sites/health/files/programme/docs/midtermevaluation-3hp_opc-summary.pdf

implications, potential for mutual learning and highlighting EU added value, and finally a voluntary exchange between Member States as of November 2017 to discuss best practices and other findings. The latest report concludes that *“more than 1.2 million deaths could be avoided through better public health and prevention policies or more effective and timely health care”*⁷. To become really effective and evidence-based, more detailed and up-to-date statistics will be needed, including on the links between access, input measures and actual outcomes.

By the end of 2015, the Millennium Development Goals (MDGs) came to an end. They were replaced by the **Sustainable Development Goals (SDGs)**, a set of 17 goals that the Member States of the United Nations have committed to reach by 2030. Goal 3 is health-specific, even if other goals, such as addressing poverty, increasing education, providing access to water and sanitation will also have effects on health outcomes.

With regards to health, the goals are much broader than the Millennium Development Goals, and also include Universal Health Coverage and access to treatments for both communicable and non-communicable diseases. These will be integrated in the European Commission’s health action plan. Indeed, the European Union has committed to implement the SDGs: *“the EU complements Member States’ action through legislation and other initiatives on public health, health systems and environment related health problems (including air quality, chemicals and waste). Health is important for people’s individual well-being and for shaping a sustainable economy as it is key to improve labour market participation and productivity. The Commission will help Member States to reach the SDG targets, in particular reducing chronic diseases’ mortality, ensuring quality healthcare, strengthening capacity to prevent and manage global health threats (including antimicrobial resistance), ending HIV/AIDS and Tuberculosis (and reducing Hepatitis), and implementing the Framework Convention on Tobacco Control”*⁸.

In recent years health was kept in the EU spotlight through debates on **EU ‘hard’ legislation**. This is now very much in the implementation phase and Member State roll out stage, as illustrated by cross-border healthcare (the next European Commission report on the operation of the Directive is due in the autumn of 2018), pharmacovigilance (ongoing roll out), falsified medicines (the delegated Regulation, and the new medicine verification system it lays down, will apply as of 9 February 2019) and clinical trials (the Regulation comes into operation in 2018). Member States’ implementation gives EPF an opportunity to highlight what these key pieces of legislation mean in practice for patients.

When it comes to **soft law**, its impact (e.g. recommendations and communications) is always harder to predict, but can nonetheless directly impact patients in very significant ways. In this context, it will be very important to monitor follow-up to EU initiatives such as the EU Joint Action on eHealth or the EU Joint Action on Chronic Diseases.

The **forthcoming Presidencies of the Council of the EU** also constitute good opportunities to raise key topics of interest to patients on the EU agenda. The only reference to health in the European Commission’s 2017 work programme is the plan to introduce an initiative on coordinated health

⁷ Health at a Glance: Europe 2016, OECD, November 2016

⁸ European Commission Communication: Next Steps for a Sustainable European Future, November 2016

technology assessments. This is expected towards the end of 2017. Although it is not mentioned in the work programme itself, the European Commission will also launch a New Action Plan on Antimicrobial Resistance in 2017. The European Commission's second report on the Paediatric Regulation is also due in 2017.

Finally, the **European Innovation Partnership (EIP) on Active and Healthy Ageing**, whose objective it is to add by 2020 two healthy life years to the average healthy life span of European citizens, continues its course.

2.4 FUTURE OF HEALTH COLLABORATION

Even if EU competence in health continues to be restricted by the Treaty, meaning that the organisation of health systems and delivery of healthcare remain Member States' competences, the European institutions still have room to manoeuvre in shaping health policy. Some stakeholders interviewed highlighted their concerns about whether or not public health will remain a priority at EU level. Certainly, the current European Commission term does not seem to prioritise health. However, EU-level collaboration in health continues, driven by most Member States' recognition of its added value to address major challenges. These are notably demographic ageing, the rise in chronic diseases determined by both age and other health determinants, and how this impacts the sustainability of national health systems.

On the occasion of the 60th anniversary of the Treaty of Rome, an editorial in *The Lancet* gave a good overview of the health achievements and challenges for the European institutions⁹. Tobacco control, the development of European guidelines for professional bodies to promote evidence-based management of a wide range of conditions, the existence of a dedicated Directorate General DG SANTE whose specific mission it is to protect and promote the wellbeing of its citizens through public health, food safety, and consumer protection, the establishment of European Reference Networks, the European Medicines Agency, the European Centre for Disease Prevention and Control, and the health impact of the European Food Safety Agency, are just a few of the examples mentioned in the article.

2.5 THE VOICE OF THE PATIENT IN THE POLICY AGENDA

At European level, patients are well-established as a legitimate and valued stakeholder group, and EPF is recognised as the prime representative organisation across chronic diseases. The European Commission is increasingly consulting citizens on new policies, and requests for input are received on an increasing number of diverse policy areas – touching on health either directly or indirectly.

Patients' rights are recognised and patient organisations are set up and strengthened in many Member States. However, patient involvement in policy-making is still limited and there is a gap between the European and national levels in the extent to which patients and patient organisations

⁹ *The Lancet*, March 25, 2017

are involved in health-related policies.

Industry funding of NGOs including patient organisations continues to be an issue of public debate. A draft European Parliament’s report says that the way EU taxpayer money is used to fund NGOs should be “*comprehensively and credibly documented*”. It is unclear as of now whether the report will go beyond a ‘draft’ status. Returning a criticism often levelled at corporate lobby groups, the report also calls on the European Commission to introduce requirements for NGOs to publish the details of the lobbying contacts they have with EU officials and MEPs on an annual basis. The discussion with specific regards to the funding of patient organisations was reopened for debate based on two reports, one published in the Journal of the American Medical Association (JAMA)¹⁰ and one in the New England Journal of Medicine (NEJM)¹¹, and in a publication in the British Medical Journal (BMJ)¹².

Patient-centeredness is recognised as one of the “common operating principles” of European health systems. However, in practice its application varies across the EU. Indeed, patient-centred care is often approached superficially, focusing on consumer “choice” and “satisfaction”, with user feedback as a tick-box exercise. An important barrier to the actual implementation of patient-centred healthcare is the lack of a common understanding of what this really means and how to implement it. Still, the concept of “patient-centricity” has become one of the key concepts in the discourse of pharmaceutical companies, with some companies already actively engaging patient perspectives throughout the company’s value chain, from early discovery over clinical trial design and patient reported outcomes to market access discussions. Even if this is still a new territory for many companies, the direction has been set.

2.6 CONSEQUENCES

The current political debate is pivotal for the role of the EU in the future. President Juncker wants to create clarity and obtain a strong and workable commitment from the Member States about the role of the EU and its institutions. Within that debate, health policy does not appear to be a priority. If this trend was to be confirmed, the consequences at Member State level could be substantial. It may have an impact on how health systems are organised, how new technology will be assessed, and ultimately how patients will have access to treatment and healthcare services. Even if the EU action in health was focused on health promotion and prevention, patients across the region would benefit from a more coordinated and harmonised approach for universal health coverage, access, and cost-effectiveness evaluation. Patients would benefit when knowledge and best practices are shared among health actors in the region, when collaborations take place that look at best possible outcomes for patients at an affordable cost.

The stakeholders interviewed are relatively optimistic. As one of them put it: Big countries have the

¹⁰ McCoy MS, Carniol M, Chockley K, Urwin JW, Emanuel EJ, Schmidt H. Conflicts of interest for patient-advocacy organizations. *N Engl J Med* 2017

¹¹ *N Engl J Med* 2017

¹² Industry links with patient organisations - *BMJ* 2017;356 : j1251

capacity to deal with issues, small countries have no capacity so they have an interest to join - there is a natural incentive to cooperate.

3. Economy

After the financial and economic crisis of the beginning of the decade, all international organisations (IMF, World Bank, European Union) now predict a stable economic growth of 1.4 to 1.8% per annum until 2020. The International Monetary Fund (IMF) adds a caveat based on the change of power in the United States: *“However, there is a wide dispersion of possible outcomes around the projections, given uncertainty surrounding the policy stance of the incoming U.S. administration and its global ramifications¹³”*.

Europe’s relative economic power is also forecast to wane, accounting for much less than 20% of the world’s GDP in 2030, down from around 22% today¹⁴.

Society makes slow progress towards more prosperity, with a slow convergence between Western and Eastern Europe. European citizens are among the healthiest, wealthiest, and safest in the world. Globally, 15 of the top 20 most prosperous countries are European: Norway (second) leads Western Europe, while Slovenia (20th) is ranked as the most prosperous country in Eastern Europe. One of the keys to Eastern Europe’s prosperity deficit lies in its poor scores in Governance and Social Capital¹⁵.

Within this economic framework, the expected growth of public healthcare expenditure is within a range of 7.2 to 7.5% of GDP by 2020, from the current 7.1%, depending on a range of cost-containment scenarios applied by the Member States¹⁶. This means an estimated growth rate of 4% per year for the European healthcare system, from € 1,400 billion in 2015 to € 1,700 billion in 2020¹⁷.

Total health expenditure in Europe on average is at 10% of GDP¹⁸, totalling 1,300 billion euro. It is on average relatively stable, even if there are some major shifts within countries, with Luxembourg, Denmark, Lithuania, Latvia, Estonia and Austria increasing their relative expenditure, and Greece, Portugal, Hungary, Slovakia, Sweden, France and The Netherlands decreasing their relative health expenditure¹⁹. When calculated in per capita expenditure, all health expenditures are stable or slightly increasing over the past five years.

Total healthcare spending is expected to rise slightly, to reach 10.5 % of GDP in 2020²⁰. Public health expenditure has continued to grow in the European Union, reaching 15% of all government

¹³ IMF World Outlook, 2017

¹⁴ European Commission - White Paper on the Future of Europe, 2017

¹⁵ Legatum Prosperity Index, 2016

¹⁶ European Commission: Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, October 2016

¹⁷ The Economist Intelligence Unit, World Industry Outlook, 2016

¹⁸ OECD Health Statistics 2016; Eurostat Database; WHO, Global Health Expenditure Database

¹⁹ OECD Health Data, accessed April 2017

²⁰ World Industry Outlook, Healthcare and Pharmaceuticals, The Economic Intelligence Unit, June 2016

expenditure on average²¹. All this means that healthcare expenditure will continue to grow at a faster pace than national income, leading to continued pressure on government budgets.

Pharmaceutical spending as a percentage of total healthcare spending has decreased over the past five years in almost every country in the EU, with Latvia as the only exception. In absolute terms, in euro per capita, pharmaceutical spending has been relatively stable²².

3.1 ACCESS TO HEALTH

Income inequality is relatively stable in the EU, with minor changes in both directions among Member States²³. Other trends may change this: demographic developments in Europe point to an increase in retired people, and a fall in the ratio of those contributing taxes to those receiving social assistance. This in turn points to a scenario of relatively better-off pensioners on the one side, and workers facing an increased tax burden on the other²⁴.

If overall income inequality is stable, it still exists, and there is a considerable body of evidence showing a close association between inequality and worse overall outcomes in health (including obesity, mental health, and life expectancy), educational performance, crime (including violent crime) and social mobility²⁵.

Although in most European Member States **Universal Health Coverage** is almost achieved in principle²⁶, there are relevant cross-country differences with regard to whom and what is publicly covered and the quality of care received²⁷. Barriers to access include affordability, waiting times and travelling distance, as well as socio-economic and cultural factors²⁸. Out-of-pocket expenses for patients have decreased overall in the European Union over the last five years, except for Austria, Czech Republic, Hungary, Italy, Portugal, Spain, The Slovak Republic, the Netherlands and the United Kingdom²⁹. In this situation, there are profound consequences as some patients will postpone their visit to a doctor because they cannot afford treatment or because of the level of co-payments, thus putting their health at greater risk. In 2014, some 6.7 % of the population aged 16 and over in the EU-28 reported that they had unmet needs³⁰ for medical examinations or treatment, with a range of almost 0% in Austria to 13% in Estonia and 20% in Latvia³¹. On average, 2.4% cites cost as a reason not

²¹ European Commission: Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, October 2016

²² OECD Data, 2017

²³ OECD (2017), Income inequality (indicator). doi: 10.1787/459aa7f1-en (Accessed on 04 April 2017)

²⁴ European Parliament, Essays on medium- and long-term global trends, Autumn 2016

²⁵ Wilkinson and Pickett (2009)

²⁶ OECD - Universal Health Coverage and Health Outcomes, July 2016

²⁷ European Commission - Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, October 2016

²⁸ European Commission: Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, October 2016

²⁹ World Bank, 2017

³⁰ Discussion on what is "Unmet Medical Need" needs to fully integrate indicators as seen from a patient perspective. See EPF's Position Paper on "Defining and Measuring Access to Healthcare: The Patients' Perspective", 2016

³¹ Eurostat, 2016

to seek healthcare access. In 6 Member States, more than 5% of the population report not seeking medical support due to monetary constraints (Latvia, Greece, Romania, Italy, Cyprus, Bulgaria, Poland, Portugal and Ireland)³². Comparable results were obtained by the European Patients' Forum *Survey on Access to Healthcare*, which demonstrated that about 60% of respondents faced financial difficulties at least sometimes as a result of spending on healthcare³³.

All this means that there is a need for **a shift towards alternative financial and business models**. *“Health systems traditionally have addressed cost management issues by optimising their supply chain and revenue cycle, using bulk purchasing, improving records management, reducing labour expenditures, and improving clinical efficiency. These approaches can be effective at improving short-term margins but they are not truly transformational. Forward-looking health systems are taking a more critical look at their existing financial/ business model to determine how best to shift from volume- to value-based payment methods that emphasize improved outcomes per dollar spent. Government and commercial payers are accelerating the transition through a range of alternative models designed to align with specific markets and populations, and increase provider risk-sharing across the ecosystem³⁴”*. The debate on payment and pricing will continue to be one of the top political priorities in the coming years.

Despite these increasing costs, the OECD published a report which stipulates that *“Overall, evidence suggests that up to one-fifth of health spending could be channelled towards better use³⁵”*. Tackling this waste will release resources, put value at the core of the policy debate, and pave the way for the re-engineering of health systems: patient centredness, streamlined hospital infrastructure, etc.

On the other hand, investing in healthcare represents an opportunity for economic growth. Work hours lost to ill-health currently cost 2.5% of GDP every year and impact all levels of the economy. In short, *“reforms are needed to help health systems survive³⁶”*. Appropriate investment in health systems is an effective way of improving health and wealth by saving lives; creating societal well-being and supporting healthier and therefore more economically active societies.

Citizens continue to prioritise health as their top concern, and so far, clearly continue to support universality and solidarity in healthcare. Health remains a key determinant of a happy life, and it remains very high on every citizen's agenda. *“With a proportion of people with low satisfaction of 65.9 % in the group with very bad health, health status is the most notable predictor for general life satisfaction. Nothing, not even unemployment or material deprivation, puts life satisfaction in danger as much as bad health³⁷”*.

As highlighted in one stakeholder interview, the fact that health is a low priority in the EU treaty, while

³² Eurostat, 2017 (2014 data)

³³ European Patients' Forum - Access to Healthcare, December 2016

³⁴ Deloitte, Health in 2016

³⁵ OECD - Tackling Wasteful Spending on Health, 2017

³⁶ Strategic Plan 2016-2020 of the Commission's Directorate-General for Health and Food Safety

³⁷ Eurostat: Quality of life in Europe - facts and views - overall life satisfaction, 2015

at the same time being very high on the citizens' agenda, creates a gap in terms of the expectations, that is not properly reflected on the EU policy agenda.

3.2 CONSEQUENCES

Increasing healthcare costs will continue to put pressure on public health budgets. Cost-effectiveness can be gained by identifying and doing away with non-value interventions and treatments. This can be achieved by increasing the focus on actual health outcomes, combined with a clear analysis and metrics of money spent per unit of generated outcome. Technology and Big Data could help in increasing efficiencies. For the patient community, the biggest challenge will be to continue to create a health policy environment that is focused on health performance and patient-reported outcomes as the single most important priority, with the question of how the system should be financed and how efficiencies should be sought as a secondary and subservient area of attention. The budget pressure should not lead to short-term savings to the detriment of encouraging much needed long-term and patient-centred innovation.

4. Technology

In the technology area, changes are taking place rapidly. The double trend of deepening and broadening insights may accelerate health outcomes for patients. The deepening is taking place at the scientific level, with basic research identifying the biochemical and genetic processes that cause diseases, creating an understanding that the way we categorise diseases may need to change too. Insights are broadened by the collection of Real World Evidence and Big Data at an unprecedented scale. Combining these deep insights with broad Big Data will result in a more personalised approach with precision technology to treat diseases: diagnostics will make it possible to detect and treat diseases at an early stage with higher effectiveness, better tolerability and less side effects. What seemed science fiction some years ago is becoming a reality with gene therapy and immuno-oncology treatments reaching the market.

4.1 PERSONALISED & INNOVATIVE MEDICINES

Personalised medicine is likely to be a major driver of research while information technology innovations will in turn be a major driver of personalised medicine. Rapidly increasing knowledge of the mechanisms of disease, and of the genetics and other differences between individuals and populations are predicted by some to lead to a “paradigm shift” in medicine: a shift from curative to pre-emptive and from disease-centred to person-centred medicine.

This is a gradual process and is likely to take at least 20 years if not more: it is also difficult to predict and riddled with uncertainty. Personalised medicine has the potential to make treatment more precise, reduce side effects, and generate savings in healthcare through eliminating needless prescriptions. Its progress is slow and the efficiencies still need to be demonstrated. Scientific developments will have political, legal and ethical implications across the whole healthcare spectrum. Patient groups need to keep a keen eye on these developments. The EU Framework Programme for

Research and Innovation (Horizon 2020) includes personalised medicine as a priority area. Framework Programme 9 is currently being discussed and the initial scoping will be done by early 2018. Other relevant EU initiatives include the European Innovation Partnership on Healthy and Active Ageing, and the Innovative Medicines Initiative (IMI).

Research investments by the pharmaceutical industry continue to increase, with an expected 150 billion euros by 2020³⁸. The number of approvals by the European Medicines Agency is increasing too, a trend which is expected to continue. The largest number of trials are currently conducted in the areas of oncology, anti-infectives, central nervous system, and diabetes/obesity³⁹. Many new pharmaceuticals are focused on smaller subgroups of patients, and the resulting high prices are a cause of public debate. At the same time, efforts are made to increase the effectiveness and cost-efficiency of the treatments by using biomarkers and by using real world evidence once the product has been launched.

Recent years have seen in the increase in very expensive innovative medicines, especially for the treatment of hepatitis C and cancer. Within Europe, Health Technology Assessment Agencies are further aligning their approaches. The criteria set by the Member States may differ significantly. Learned societies have also established Value Assessment Frameworks to evaluate the value of new pharmaceutical treatments, especially in oncology. Systems were proposed by organisations such as the American Society of Clinical Oncology (ASCO), the European Society of Medical Oncology (ESMO), and the Institute for Clinical and Economic Review (ICER). The debate about how to establish a common framework - and whether this is desirable at all - will continue in the coming years. Even the question of whether Intellectual Property Rights on medicines are desirable was again opened for debate by the United Nations High-Level Panel and by an OECD consultation. This is a cause for debate: many argue that innovation should not be hampered. Even if research priorities for medicines have been set by WHO, we must recognize that the task division between public and private research on achieving results for both commercially profitable and non-profitable medicines has never taken place.

Despite the obvious role of prevention and lifestyle choices in avoiding both infectious and chronic diseases, technology will remain critical to achieve overall health gains.

Deloitte identifies ten technologies that hold the promise to obtain more with less in the coming years: next-generation sequencing (NGS), 3D-printed devices, immunotherapy, artificial intelligence (AI), point-of-care (POC) diagnostics, virtual reality (VR), leveraging social media to improve patient experience, biosensors and trackers, convenient care and telehealth⁴⁰. Despite the “more-is-less” claim, some innovations such as immuno-oncology will lead to significant increases in the healthcare budgets, in parallel with equally important health outcomes. Other fascinating avenues are being explored, including the use of nanobots, the study of the microbiome and the use of liquid biopsies to

³⁸ EvaluatePharma, 2016 - World Preview 2016, Outlook to 2022

³⁹ PharmaProjects 2014; McKinsey analysis

⁴⁰ Top 10 health care innovations: Achieving more for less, Deloitte Center for Health Solutions, 2016

trace cancer. Some even claim that all cancer will be eradicated by 2050 for all people under 80 years old⁴¹.

4.2 DIGITAL HEALTH

E-health and digital health should help to redefine the way we look at outcomes. They hold the promise to have more data available, better monitoring of results, identifying real world effectiveness and best practices at points of care. These may add additional information on outcomes that really matter to patients, such as pain management or quality of life. However, to reap the benefits of these technological advancements, health literacy, **e-literacy** and patient involvement are crucial to realising technological innovation in a way that meets patients' needs. Patients' expertise, which is based on their experiential knowledge, is starting to be recognised as equally valid and complementing scientific knowledge. Patient input into research and development is an opportunity to develop new treatments and technologies that better meet patients' needs and are also cost-effective.

eHealth will continue to be a priority area of EU health policy. eHealth records controlled by the patient and technologies such as personalised remote monitoring devices and novel communication solutions have the potential to empower patients to take control of their own healthcare and play an active role in the patient- health professional relationship. Nanotechnology, especially nanodevices – non-invasive devices to monitor individual persons' health status - may be developed to use in personalised healthcare.

4.3 THE CHALLENGE OF HEALTH RESEARCH AND DATA PROTECTION

Future biomedical and public health research, the development of personalised medicine, and eHealth have implications for the use of **patients' data**. There is increasing recognition that medical data needs to be more widely shared. Furthermore, personalised electronic health records may in future contain genomic and lifestyle data. Legal and ethical issues include for example privacy and confidentiality, informed consent, use of individual data for research, access to patient data by e.g. insurers, and discrimination based on health status/genetic profile.

“The current challenge in digital healthcare is no longer purely about technology. Companies have to figure out how to initiate entire healthcare ecosystems to adopt new technology-enabled ways of meeting the innumerable challenges faced in healthcare^{42”}. However, for digital health to take off, there must be a fundamental shift in how stakeholders collaborate, and how they look at their own role in the system.

The lack of trust in the system may lead patients to take up their own responsibility and become more empowered: *“Individuals—as consumers, citizens, and independent actors—are radically empowered*

⁴¹ Overcoming Cancer in the 21st Century, University College of London, 2015

⁴² Economist Intelligence Unit - Digital Health - Total Convergence, 2017

by new technology and increasingly available information, leading to soaring expectations for services, transparency, and rapid change—particularly among the younger, digital-native millennial generation. Furthermore, the rise of the global middle class is leading to greater individualism and expectations for service from their governments and from businesses, with consumers having never had a broader freedom of choice. The new global individual is radically empowered, inspired to question existing standards and institutions, and expects to be part of rising global prosperity”⁴³. We also see the emergence of individual patient advocates, who network with each other but not necessarily with patient organisations – and are doing “radical” things with technology⁴⁴.

Digital technology offers a great opportunity for individual patients, but also for healthcare providers and the patient movement to come with different perspectives to healthcare consumption and optimal treatment pathways. *“Patient openness to sharing data is at the crux of the success of big data in healthcare. (...) Health information exchanges will also need to develop strong consent processes.”* Patients Know Best puts patients in control of their medical records through the world’s first online patient portal with an inbuilt consent engine. The system gives patients the flexibility to invite their doctors and caregivers to view their medical records while adjusting privacy levels for different categories of data. For example, patients can choose to share general health information but to restrict access to data on their mental health to select groups of people⁴⁵.

“The global digital health market accounted for \$55,332.5 million value in 2014, and it is expected to grow with a CAGR of 21.4% during 2015 - 2020. Among the various technologies, the digitised health system segment dominated the global digital health market, with 48.2% share in 2014. The global market of digital health is up surging with a significant rate, due to increasing demand for advanced healthcare information system, and growing investments by HIT players. The technologies, such as electronic health records (EHR), telemedicine, and mHealth, help in compiling services related to diagnosis, treatment, care, and rehabilitation. They improve communication between patients and healthcare providers, in order to reduce medication errors, and provide better coordinated care”⁴⁶.

“The global mHealth market was valued at \$10.5 billion in 2014 and is expected to grow at a CAGR of 33.5% during 2015-2020. The mHealth market is in its nascent stage and is expected to yield significant revenues with increasing awareness and favourable regulatory impositions specific to the quality and feasibility of mobile-based medical devices. Penetration of mobile phones in healthcare segment has had a significant impact on the overall healthcare industry”⁴⁷.

Better medical equipment, innovative and better tolerated treatments, and monitoring have in recent years created a move away from hospitalisation to home care. We can expect this to increase in the

⁴³ AT Kearney: Divergence, Disruption, and Innovation, 2015

⁴⁴ Interesting examples include Sara Riggare <http://www.riggare.se>, Tim Omer aka the “Diabetic hacker” <http://www.hypodiabetic.co.uk>, Dave DeBronkart (e-patient Dave) <http://www.epatientdave.com> and Paul Buchanan <http://www.bmj.com/about-bmj/advisory-panels/patient-panel-members/paul-buchanan>

⁴⁵ EIU - Digital Health - Total Convergence, 2017

⁴⁶ Global Digital Health Market Size, Share, Development, Growth and Demand Forecast to 2020

⁴⁷ Global mHealth Market - Size, Industry Analysis, Trends, Opportunities, Growth and Forecast, 2014-2020, Allied Market Research

coming years. Denmark set the example and has now over 25 years of experience with the home care, which can even deal with complex treatments such as chemotherapy and dialysis. Initial evidence shows that one-third of patients can remain at home, avoiding re-admission to a nursing home or hospital, thereby delivering cost-savings of up to €740 a day⁴⁸.

4.4 CONSEQUENCES

Some claim that we are at another historic juncture in biomedical sciences, when basic research is further integrated with newest technology combining molecular, genetic, engineering and informatics into integrated solutions. In this context, it is critical for patient organisations to become involved and to understand the consequences and potential of the new trends in health research and technologies, and to voice the patient perspective, making sure that this progress is led by increased and meaningful outcomes for patients.

In the shorter term, some of the stakeholders have suggested that EPF take a more prominent role in the digital space, not only at the policy level, but also at an operational level, facilitating the collection of European patient expectations and data through new technologies such as crowd-sourcing or a European version of “PatientsLikeMe”.

5. Society

Good health remains one of the top priorities among European citizens. In the 2016 Eurobarometer, ‘Health and social security’ is mentioned as the most important concern at national level by 18% of EU citizens and stands in fourth place of all topics, but is the first answer given in six Member States, led by the Netherlands (49%), Latvia (42%) and Estonia (41%), Hungary (33%), Poland (33%), Romania (32%), the United Kingdom (27%). When asked what people as individuals are most confronted with, health scores high in Finland (37%) and Sweden (42%), Netherlands (35%) and Latvia (35%)⁴⁹.

5.1 DEMOGRAPHIC CHANGE

Rising demand and associated spending are being fuelled by an ageing population; the growing prevalence of chronic diseases and co-morbidities; development of costly clinical innovations; increasing patient awareness, knowledge, and expectations; and continued economic uncertainty despite regional pockets of recovery⁵⁰.

The population will continue to increase from 507 million now to 512 million people in the whole of Europe in 2020. The share of people aged 65 and over is projected to increase from 18.9 % in 2015 to 28.1 % by 2050, with the share of people aged 85 and over more than doubling from 2.5 % in 2015 to

⁴⁸ Royal College of Nursing, RCN Policy and International Department, “Moving Care to the community: an international perspective”, 2013

⁴⁹ Eurobarometer 2016

⁵⁰ Healthcare And Life Sciences Predictions 2020: A Bold Future?, Deloitte, 2014

6.0 % by 2050⁵¹. A further decrease of the working population is expected with 21 million people by 2030⁵².

Chronic diseases are on the rise, assisted by rapid urbanisation, sedentary lifestyles, changing diets, and rising obesity levels. By 2020, 50% of global health care expenditures—about \$4 trillion—will be spent on three leading causes of death: cardiovascular diseases, cancer and respiratory diseases. In Europe, these three diseases continue to have the highest mortality statistics: cardiovascular diseases accounts for 34% of all deaths, followed by cancer with 30% and respiratory diseases with 8%⁵³.

From 2015 to 2050 the **prevalence of dementia is forecast to increase** in every region of the world. In 2015, 46.8 million people worldwide are estimated to be living with dementia. This number is anticipated to double every 20 years, reaching 74.7 million in 2030 and 131.5 million in 2050⁵⁴.

Chronic diseases affect more than 80% of people aged over 65 years (> over 100 million citizens) and cause nine out of ten deaths in Europe. They carry significant human costs (human suffering, reduced workforce, social exclusion, health inequalities etc.). As a consequence, chronic diseases absorb 70% to 80% of health costs corresponding to €700 billion in the EU. This is expected to rise in the coming years as unhealthy lifestyles contribute further to the chronic, disease burden⁵⁵. According to an OECD report, the over-65 age group accounts for 40-50% of healthcare spending and their per capita healthcare costs are three to five times higher than for those under 65. And there are fears that public expenditure could rise as ageing in OECD countries accelerates⁵⁶. *“With a median age of 45, Europe will be the “oldest” region in the world by 2030⁵⁷”*.

5.2 HEALTHY LIFE YEARS AND MULTIMORBIDITY

The fact that we now live longer doesn't always mean that we live in good health. Today, the average person in an OECD country can expect to live 20 years longer than in 1970; in the EU life expectancy increased by five years between 1990 and 2012. A good share of the population can now expect to live in excellent health until over 80. Yet over 60% of people aged between 65 and 74 suffer from at least one chronic condition, and from the age of 75 many have three or more. By 2050, one in ten people in the OECD area will be aged over 80, compared to 4% today⁵⁸. Especially among senior citizens, the risk of multimorbidity is high. *“Nearly every second person over 60 years old suffers from more than one illness⁵⁹”*.

⁵¹ Eurostat, 2017

⁵² ScienceBusiness, 2015

⁵³ Health at A Glance, 2016 - OECD and European Commission

⁵⁴ Facing the tidal wave: De-risking pharma and creating value for patients, Deloitte Centre for Health Solutions, 2016

⁵⁵ Friends of Europe: Adapting EU Health Policy to an Evolving Europe, 2015

⁵⁶ Petra Marešová, Hana Mohelská, Kamil Kuča, Economic Aspects of Ageing Populations, Procedia Economics and Finance 23, 2014

⁵⁷ European Commission: White Paper on The Future of Europe, March 2017

⁵⁸ OECD, 2017

⁵⁹ Holte, H. & Albrecht, M. (2004) Verkehrsteilnahme und -erleben im Strassenverkehr bei Krankheit und Medikamenteneinnahme. Berichte der Bundesanstalt für Strassenwesen, Mensch und Sicherheit, Heft M 162. Wirtschaftsverlag NW, Bremerhaven

At the same time, relative mortality rates for the major diseases keep moving downward. Mortality rates for cardiovascular diseases, cancer, infectious diseases, metabolic diseases show a steady decline over the past years. This decline is expected to continue, as the result of earlier and better diagnosis, better treatments, increased monitoring and care.

5.3 CARERS AND HEALTHCARE PROFESSIONALS

We must not forget the role of carers, in particular with an increasingly ageing population – **the role of carers becomes even more important**. A substantial part of long-term care (LTC) is provided by untrained informal carers, and long-term care provision is usually a combination of informal and formal care. The European Commission acknowledges the added-value of EU level action in the field of carers. The WHO identifies the position of carers as one of the key issues in dementia. The European Pillar of Social Rights presented by the European Commission in April 2017 includes a proposal for a Directive on Work-Life Balance for Parents and Carers.

Migration of health professionals across the EU is increasing, leading to influx of immigrant health workers in some EU Member States, and shortages in others. New types of health professionals are needed, with new skills including technology and patient-centred skills. The European healthcare systems also face important challenges with huge economic consequences if they are not adequately addressed: the EU will need, for example, 1 million new health professionals by 2020⁶⁰.

5.4 THE IMPACT OF TECHNOLOGY ON SOCIETAL TRENDS

Society has changed in such a rapid way that healthcare systems seem to be trying to catch up. The increased digital literacy and connectedness lead to self-diagnosis, self-monitoring and will have a profound effect on how the health ecosystem works. Patients will discuss amongst themselves through online conversations about what works for them or not.

Communication technology is a major driver of patient empowerment and networking. Patients can access more and more information and communicate rapidly with each other and with health professionals. The “e-patients” phenomenon from the US and Canada is spreading to Europe. Empowered, informed patients are driving a cultural shift in the patient’s and health professionals’ role. “E-patients” advocate for a “participatory medicine” model where “networked patients” become responsible drivers of their health, and in which healthcare providers encourage and value them as full partners.

A new trend that emerged in the past few years is the “**sharing economy**”, sometimes called disruptive in the sense that it breaks with the traditional economic actors, with Uber and AirBnB cited as the most known examples. There are not many examples for disruptive or shared companies in healthcare

⁶⁰ Strategic Plan 2016-2020 of the Commission’s Directorate-General for Health and Food Safety

yet, but initiatives such as PatientsLikeMe start to get followers with Patientory, a Facebook-based community for peer-to-peer patient communication as well as a secure platform to share health data with providers and insurers.

Patients have an opportunity to become truly a part of the solution in the creation of future healthcare systems by demonstrating the value of patient involvement. On the other hand, with the focus on health promotion and prevention, health is increasingly seen at EU level as concerning citizens and populations, not only patients. Predictive/ preventive, personalised medicine will further shift the focus on to the citizen who is not (yet) a patient.

We are seeing also tendencies towards a more consumerist approach to health – an increased focus on “well-being”. The well-being concept is being stretched by commercial providers to encompass for example certain cosmetic medical procedures, nutritional supplements etc. presenting health increasingly as a lifestyle issue. Consumerism combined with the idea that lifestyle factors can cause various chronic diseases, is shifting discussions towards “individual responsibility” over one’s health. Health literate / informed patients and citizens will be expected to take good care of their health, thus cost less to the healthcare services. Many chronic diseases however do not result from lifestyle factors. In the medium to longer term and under the current economic circumstances, there is a risk that patients may increasingly be stigmatised for having a disease and thus considered a burden on healthcare resources and requested to bear the costs themselves.

5.5 CONSEQUENCES

Two major trends will continue in society: the ageing populations and a different connectedness through technology. People will live longer and often better, with an increasing professionally inactive population relying on the taxes paid by a decreasing working population.

Social and cultural changes will follow the same trend as over the past years, with people more and more being connected digitally to communities of like-minded peers. Patients can connect and do connect with communities that cross geographical boundaries. At the same time, the political trend to fall back on national priorities and national decision-making could run counter to this digital evolution.

Still, the communities allow for common approaches and the identification of technology and systems that bring results. They will almost spontaneously advocate for change as the best possible solutions will rise to the surface in this digital debate. It is a force that can be tapped into if properly managed.

6. Glossary

BMJ – British Medical Journal

EMA – European Medicines Agency

EIP – European Innovation Partnership

EPF – European Patients' Forum

ERN – European Reference Network

EU – European Union

HSPA – Health Systems Performance Assessment

HTA – Health Technology Assessment

IMI – Innovative Medicines Initiative

LTC – Long Term Care

NHS – National Health Service

OECD – Organisation for Economic Co-operation and Development

SDG – Sustainable Development Goals

WHO – World Health Organization