AmCham EU position on the Communication on effective, accessible and resilient health systems[1]

Building effective, accessible and resilient health systems in Europe

POSITION PAPER

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) supports the European Commission's view that health systems play a central role in modern societies in helping people maintain and improve their health. The purpose of this position is to share AmCham EU's recommendations in light of the European Commission's proposed actions to: a) support effective health systems; b) increase healthcare accessibility; and c) improve health systems resilience across EU Member States.

Greater uptake of healthcare innovation in Europe, a more predictable framework for the healthcare industries and a strengthened role for consumers in healthcare are key prerequisites to ensure that EU health systems are more accessible, effective and resilient.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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[1]Communication of European Commission of 4 April 2014: Effective, accessible and resilient health systems, COM(2014) 215 final

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Over the past 60 years, healthcare innovation has played a significant role in ensuring Europeans live longer with a greater quality of life. It has contributed to helping healthcare systems across Europe address the challenges posed by infectious diseases and chronic conditions. While Europe faces an unprecedented set of demographic, fiscal and health challenges, it is critical that the healthcare industry continues to support improvement of the wellbeing and productivity of Europeans. Health is an important driver for wealth as outlined in an earlier AmCham EU position on 'Investment in Healthcare'.[2]

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Supporting effective health systems

If today's healthcare model continues unchanged, it is likely to experience an unprecedented escalation in costs and demand. There is a need to transform healthcare systems to maximize value for patients: that is, achieving the best outcomes at the lowest cost.

AmCham EU encourages the Commission to continue to explore and facilitate a discussion at European level on how health systems can be shaped to improve health outcomes in an efficient way. The Commission's proposed action to support Member States' collaboration on Health Systems Performance Assessment (HSPA) is needed. Collaboration on HSPA should provide Member States with the necessary tools and methodologies to make national health systems more effective. As part of this discussion, the Commission should consider how the uptake of innovative healthcare products can drive efficiencies, improve productivity and facilitate patient-centric care. In addition, for chronic conditions, improvements to self-management should be included as performance indicator (standard of care) across the EU.

AmCham EU welcomes the emphasis on integration of care to reduce further the reliance of Member States' health systems on hospital-based care. In that regard, AmCham EU recommends focusing on two key elements:

- Chronic diseases: AmCham EU would welcome a reflection on improving the role of primary care in secondary and tertiary prevention, i.e. earlier identification, early treatment of the disease and prevention of the disease's progression. This work should also include an exchange of best practices on how to improve adherence.[3]

[2] AmCham EU (2012), Investment in Healthcare; http://www.amchameu.eu/Advocacy/HealthcareCommittee/tabid/94/Default.aspx

[3] Tonio Borg, European Commissioner for Health, recognised the value of prevention in a remark made at the occasion of the 2014 EU Summit for Chronic Diseases: 'Another example of cost-effective prevention is to diagnose and treat arterial fibrillation so as to prevent stroke. This could save countless lives, with modest investment.'

- Communicable diseases: AmCham EU would encourage an exchange of best practices both on effective immunisation campaigns and on the mitigation of 'worrying signs of falling vaccination rates.'[4] As regards to'elderly people or people with chronic illnesses'[5], a focus on the immunization of the elderly population appears to be particularly appropriate.

Regarding the proposed discussion on actions to further improve patient safety and to reduce unwarranted variation between and within Member States, AmCham EU supports the Commission in following up on the Council recommendation on patient safety.[6] It supports the idea of going beyond the existing recommendations and broadening the EU agenda to address inequalities in access and quality of healthcare across the EU. Developing a European strategy on patient safety and reduction of infection rates would require the identification of effective measures to implement cost-effective solutions. These solutions could include EU-wide data collection, common metrics, mandatory reporting and legislation, as well as fostering a culture of patient safety and appropriate medical technology.

AmCham EU would also like to draw the Commission's attention to the need to ensure that the pharmacovigilance legislation is implemented in a timely and effective manner across EU Member States. More specifically, health systems must be set up to ensure that the clear identification of biologic medicines across the EU is possible. If adverse events occur, it is important for manufacturers, physicians and patients to understand as quickly as possible which product might be causing them.

AmCham EU would also like to recall potential safety issues associated with the off-label use of medicines for economic reasons.[7] As recently pointed out in an EFPIA position paper on the topic[8], off-label use, when licensed alternatives exist, can compromise patient safety as these medicines have not been tested and assessed to the same stringent standards as for their prescribed indication, putting patients' health and safety at risk for the sake of cost savings. In order to preserve the high standards of patient safety in the EU, healthcare bodies should adhere to EU law[9] and refrain from promoting off-label use for economic reasons.

Increasing healthcare accessibility

If Europe is to compete in an ever-changing global environment, policies need to be in place to ensure its citizens are well-equipped to meet the needs of the future marketplace. This will require investment in training and skills development at every stage of workers' lives to remain relevant to the needs of society and the economy.[10] For example, Health Care Professionals (HCPs) working in the oncology

[4]As pointed out by the European Commission in COM(2014) 215 final, p. 6
[5]In the framework of the scope set out by the Commission in COM(2014) 215 final, p. 13
[6]Recommendations from the Council of the EU of 9 June 2009: Patient safety, including the prevention and control of healthcare associated infections, 2009/C 151/01
[7]Court of First Instance, Artegodan GmbH and others, 26 November 2002, joined cases T-74/00 and others, para 173, http://bit.ly/LbJzcn
[8]http://www.efpia.eu/uploads/EFPIA_Position_Paper_Off_Label_Use_May_2014.pdf
Recent cases include the 17 December 2012 amendment to the French 'Code de la santé publique' (Article L-5121-12-1) to allow the government to issue recommendations encouraging on economic grounds, off-label use of a medicine despite the existence of authorised therapeutic alternatives. Similarly, on 20 March 2014 Italy adopted the Law Decree n°36 which promotes off=label use, on economic grounds, even if licensed medicines are available.
[9]As stated in Article 168 of the Treaty on the Functioning of the European Union (TFEU), 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. The European Union adopted a robust and stringent approval system for medicines which aims at guaranteeing the highest level of patient safety.'
[10]AmCham EU (2013), Agenda for Action 2014-2019 ;
http://www.3d-zeitschrift.de/p/ODdS4FlM3Xz5d/AmCham.html

area (e.g. clinical oncologists, oncology nurses) are using new treatment modalities such as immuno-oncology. However, they lack the knowledge and expertise in the immunology field, which could limit their actions in clinical settings and the potential benefits to patients.[11]

As the Commission intends to work with Member States on developing recommendations, common tools, indicators, and guidelines to support Member States' planning, AmCham EU would like to suggest that the Commission revises its 2012 Action Plan for the EU Health Workforce. Specifically, it should encourage Member States to implement its main provisions, such as improving health workforce planning and forecasting, anticipating future skills needs and improving training, recruitment and retention of health professionals.

Regarding access to medicines, as the Communication indicates, 'national decisions on pricing and reimbursement have direct and indirect impacts on the accessibility of medicines across the EU: innovative products are not always made available at the same time in all Member States, and in some countries they may not be available at all.'[12]

Equitable access to innovative treatments in the EU can be negatively impacted by the combination of international reference pricing[13] and parallel trade as laid out by AmCham EU in *The EU Single Market: A Work in Progress*.[14] In some countries, the reference pricing system is applied rigidly, while in other countries, it is only one of many elements used to inform pricing decisions. The basket of countries chosen varies, based on a range of criteria used to justify the selection of countries. More extreme versions of referencing can include referencing to countries in a vulnerable economic situation: for instance referencing to so-called 'bailed-out countries' or to countries undergoing fiscal restructuring programmes.

AmCham EU believes that confidence in the Single Market could be improved by offering differential pricing policy approaches that reflect the differences of the markets in question. Such an approach would be beneficial for patients and payers. It would also ensure the uptake of innovation, sustained investment in Europe's Single Market, and ultimately growth and job creation. From a broader perspective, pricing and reimbursement policies, access to medicines and incentives for innovation are strongly interlinked. Therefore, AmCham EU agrees with the conclusion of the Council Working Group stating that 'the role of creating predictable framework conditions for the healthcare industries to provide state of the art treatment options to European patients merits further consideration.'[14]

Considering that the Commission states that the 'EU needs a competitive pharmaceutical industry'[15] while the latest country-specific recommendations (CSRs) appear to focus on cost-cutting in the healthcare area, AmCham EU would like to encourage the European Commission to also consider ways of reconciling public expenditures with a thriving industry for the benefit of the EU. This would ensure consistency with the Commission's staff working documents 'Investing in health'.[16]

The latter Communication also points to important changes introduced by Directive 2011/24[17] and the increased interaction between health systems. This is the case for increased transparency on 'undue

[11]See : http://www.esmo.org/Conferences/Past-Conferences/Immuno-Oncology-2013/Videos and http://www.esmo.org/Conferences/Past-Conferences/Immuno-Oncology-2013/Programme
[12]COM(2014) 215 final p. 10
[13]International reference pricing is defined in this position paper as the practice of using the price(s) of a medicine in one or several countries in order to derive a reference price for the purposes of setting or negotiating the price of the product in a given country.
[14]AmCham EU (2012), The EU Single Market: A Work in Progress; www.amchameu.eu
[15]COM(2014) 215 final p. 14
[16]Commission Staff Working Document of 20 February 2013: Investing in health, SWD(2013) 43 final
[17]Commission Directive of 9 March 2011: Application of patients' rights in cross-border healthcare, 2011/24/EU

delay' for access to treatment.[18] When it comes to patient mobility and access to healthcare across the EU, Article 11(2) of Directive 2011/24/EU sets out for the Commission to adopt measures to 'facilitate the recognition of medical prescriptions issued in a Member State other than the Member State where the prescriptions are dispensed.' In December 2012, the Commission adopted a non-exhaustive list of elements to be included in those prescriptions.[19] AmCham EU invites the Commission to monitor progress on the recognition of medical prescriptions in the cross-border setting and reflect upon the possible need for the establishment of a single prescription template to be used in the EU's cross-border context.

Improving health systems resilience across EU Member States

Healthcare systems can only hope to become sustainable by faster adoption of innovative technologies which promise better outcomes at lower costs, or deliver increased productivity and quality, or preferably both.

However, there are worrying indications of a decrease in uptake of innovation within the EU. The latest industry figures on the type, number and age of diagnostic imaging equipment (the installed base) in Europe[20], highlight a worrying consequence of the broad austerity measures European countries have been exacting on their healthcare delivery systems.

These figures demonstrate that in many countries the installed base is the oldest it has ever been. This comes at a time when healthcare systems need to adjust to increased demand and when the European Commission is promoting investment in health and innovation as an essential element to lead Europe's economic recovery.

AmCham EU urges the Commission to encourage countries to invest in healthcare, to encourage the uptake of innovative technology and solutions that can help transform the delivery of care and to guard against the spectre of short-term financial accounting, which must not be allowed to jeopardise the sustainability of Europe's healthcare systems.

Health Technology Assessment (HTA) is emerging as the preferred route for national or regional bodies to assess the added 'value' of innovative healthcare products. AmCham EU looks forward to learning more and providing input to the Commission's proposals to create a more ambitious and stable structure to support scientific cooperation on HTA. Member States' cooperation can improve our shared understanding of the clinical aspects of health technologies. However, it is important to recognise the many differences in clinical practice, disease burden, disease management protocols, choice of comparator, health inequalities and health system costs across the EU. Demonstrating value through HTA has become well-established for pharmaceuticals across Europe, and now the attention is turning to medical technologies and IT. AmCham EU would like to bring the Commission's attention to the specific challenges associated with assessing a medical device or innovative medical diagnostic. Medical technology has the propensity to change the system in which it is introduced and often the 'value' proposition of such technologies cannot be measured in isolation.

Greater health systems resilience can also be achieved by investing in health literacy, eHealth and innovative technologies. AmCham EU calls for a much greater level of investment in healthcare, in particular through EU funding instruments to ensure that health standards are raised across the region.

[18]COM(2014)215 final p. 2 and 9
[19]Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State
[20]COCIR (2014), Medical Imaging Equipment: Age Profile & Density, Executive Summary

Cohesion and Structural Funds are important financial mechanisms for the EU Member States to invest in healthcare and reduce health inequalities. AmCham EU believes that the 2014-2020 funding programme offers a great opportunity for healthcare systems to be redesigned and restructured to improve in efficiency and deliver a transformational change which will enable a shift from a hospital-centred care to community-based care and integrated services. If well utilised, with sound and feasible rules and procedures in place, EU funding will continue to serve regions that are facing challenges in delivering healthcare services.

In that context, eHealth is a key enabler of reformed, more resilient healthcare systems in Europe. Innovative ICTs, including mobile and wireless technology, play a significant role in improving healthcare delivery.

AmCham EU would like to stress the importance of health literacy and the role of citizens and patients as stakeholders in health systems. The Commission's Communication on effective, accessible and resilient health systems should consider how greater health literacy can contribute to fostering effective, accessible and resilient health systems. Citizens and patients have a considerable role to play in the success of programmes promoting healthy lifestyles, prevention and better adherence. The recently published AmCham EU report *Forever Healthy: The 2020 Healthcare Consumer*[21] suggests that healthcare systems should help consumers practice self-care through healthy lifestyles, prevention and better adherence. In its approach to chronic conditions, the European Commission should consider including self-management as a standard of care across the EU.

Conclusion

Greater uptake of healthcare innovation in Europe, a predictable framework for the healthcare industries and strengthening the role of consumers in healthcare are key prerequisites to ensure EU health systems are more accessible, effective and resilient.

Medical technology and pharmaceutical manufacturers continue to developed new innovations that play a critical role in driving access to healthcare, increasing efficiency, improving productivity and progressing patient safety. However, there are worrying trends, including the latest installed base data that are showing that the timely adoption of innovative technologies by European hospitals is the slowest ever recorded.

AmCham has consistently argued for health and healthcare to be considered as an investment as it plays a significant role for creating wealth.[22] Ultimately, this contributes to the EU 2020 priorities of smart, sustainable and inclusive growth as outlined in AmCham EU's position on investment in healthcare.[23]

AmCham EU would be delighted to discuss its recommendations with the European Commission in greater detail.

[21] AmCham EU (2014), Forever Healthy. The 2020 Healthcare Consumer;
http://www.amchameu.eu/Home/FullStory/tabid/106/smid/827/ArticleID/1007/reftab/449/Default.aspx
[22] SWD(2013) 43 final
[23] AmCham EU (2012), Investment in Healthcare;
http://www.amchameu.eu/Advocacy/HealthcareCommittee/tabid/94/Default.aspx