AmCham EU response to the public consultation on the preliminary opinion on 'access to health services in the European Union'

CONSULTATION RESPONSE

Executive summary

AmCham EU welcomes the preliminary opinion of the European Commission and the Expert Panel on Effective Ways of Investing in Health regarding "access to health services in the European Union". As outlined in the Commission communication on effective, accessible and resilient health systems (European Commission (2014), *Communication from the Commission to the European Parliament and the Council on Effective, Accessible and Resilient Health Systems* COM(2014) 215), accessibility is one of the key components contributing to strong health systems with effectiveness and resilience. However, the report addresses this important issue only superficially; it focuses on limitations and variations in terms of access to healthcare and provides only little context on the impact on EU health systems and the broader economy. By limiting itself to reference existing sources and without making concrete recommendations in this area, the report thus falls short to assess the impact of access to health on the broader economy, which was the main question to the expert panel.

The purpose of this paper is to share AmCham EU's position on several issues highlighted in the opinion and to suggest constructive recommendations to strengthen it and ensure consistency with recent documents adopted at the EU level.

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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 2014 and directly supports more than 4.3 million jobs in Europe.

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Chapter 1: Issues related to financial resources

The American Chamber of Commerce to the EU (AmCham EU) welcomes the call to ensure adequate investment in health services. Taking the economic crisis into account, governments face strong pressure on their budgets as healthcare expenditures surpass gross domestic product (GDP) growth. Changes in regional demographics and the challenges associated make long-term access to health services even more critical. As indicated in our report entitled *Forever Healthy: The 2020 Healthcare Consumer*, current healthcare funding models are not sustainable as citizens will need to make a greater financial contribution towards their treatment. The current economic crisis presents thus an opportunity to rethink the status quo in healthcare but it should be done with a more long-term perspective and in-depth assessment of policy options.

Health is essential, not desirable, if an economy is to prosper. There is no growth when workers become ill. There is no increase in productivity when ill workers must stay in recovery longer than necessary. Eventually, demographic changes and a smaller taxpayer base will have even harsher consequences on the future of healthcare, unless health services are adequately funded and prevention measures carried out.

A recent study in Germany entitled *Innovation Impulses of the Healthcare Industry* argues that billions of euros could be saved by investing in health technology. The study explains that increasing health spending by €101 billion between 2002 and 2008 was more than compensated for by a gross added value of €123 billion over the same period – a positive balance for the economy as a whole, according to the government's analysis. The study shows that investing in medical innovation resulted in a decrease in lost working years, thus preserving productivity.

Recommendations:

- Include a call for action for national ministries to develop joint budgeting mechanisms, thus addressing the current silo approach (e.g. health and social affairs, education, and economic and budget ministries) (page 25).
- Include a call for action for Member States to develop policies and incentive mechanisms to mobilise employers and occupational health professionals to incorporate prevention and early intervention in the work place (page 25).

Chapter 3: Issues related to appropriate and cost-effective services

AmCham EU welcomes the recommendation to make investment in healthcare more cost-effective. We believe that a very good example of forward-looking investment in healthcare is offered by policies that empower citizens and patients to choose behaviours that are 'health-beneficial'. One way to do this is by improving health literacy and patients' access to the healthcare system. Today access to health information and online services for families and individuals are easier than ever and can play a powerful role not just in the prevention, but also in the treatment and management of diseases. Most importantly, it can be done at low or no cost. This should be part of a comprehensive strategy to put citizens at the centre of their health, gradually shifting emphasis from 'patients' to 'citizens'. We believe that access to health services can be further improved if patients will play a more active part in making informed decisions about their healthcare.

However, healthcare systems are by and large still based on responding to acute problems by testing, diagnosing and relieving symptoms (World Health Organisation (WHO) (2002), Integrating Prevention into Health Care, *Fact Sheet* n. 172). This model of care does not reflect the well-known fact that major causes of illness such as tobacco smoking, poor diet, physical inactivity and abuse of alcohol could easily be avoided. Similarly, preventive screenings and vaccines can reduce mortality either at a low cost or at a cost saving (Joshua T. Cohen, Peter J. Neumann and Milton C. Weinstein (2008), 'Does Preventive Care Save Money? Health Economics and the Presidential Candidates', *The New England Journal of Medicine*, 358:1, pages 661-663).

The paragraph on 'medicalization' can be misleading as it seems to stipulate a legal context which does not exist in Europe (e.g. 'Some domains of daily life are increasingly subjected to medical definition and jurisdiction, often as a result of "disease mongering", a process in which interested parties create public awareness of and demand for specific treatments through direct to consumer advertising, use of the news media and other strategies' (Moynihan and A. Cassels (2005), *Selling Sickness: How the World's Biggest Pharmaceutical Companies are Turning us All into Patients*, United States, Nation Books, lines 1,896-1,908). In contrast to the US, direct-to-consumer advertising (DTC) is forbidden for prescription medicines. DTC may be done for non-prescription medicines; however, such non-prescription medicines usually have no impact on the publically funded health budget. Since the chapter is about 'relevant, appropriate and cost-effective spending in the public sector', this paragraph should either be deleted or explain to what extent it concerns 'publicly financed benefits' (line 1,705).

Recommendation:

- Rephrase the paragraph on over-medicalisation, which seems to stipulate a legal context which does not exist in Europe.

Chapter 4: Issues related to health facilities

AmCham EU believes that m-health and e-health should be further explored within this chapter. Benefits associated with m-health and e-health adoption are twofold. On the one hand, they would contribute to the modernisation of healthcare systems by improving efficiency, safety, quality and reducing clinical and administrative costs. On the other hand, e-health would contribute to citizens' empowerment, notably in terms of control over their health information and associated services, and guide the distribution of public services towards a fully digital society. This will in turn improve quality of life and boost Europe's competitiveness based on innovative business models. The implications for consumer welfare would be considerable in terms of increased accessibility, transparency and competition in the provision of both public and private services, including in a pan-European dimension.

Modern technologies in the field of e-health and m-health offer many solutions which do not only improve access but are also very cost-effective (see e.g. Klasnja, Predrag, Pratt, Wanda (2012), *Healthcare in the pocket: Mapping the space of mobile-phone health interventions*, Journal of Biomedical Informatics 45/2012, p. 184-198; or European Commission (2014), *Green Paper on Mobile Health Services* (mHealth) - COM(2014) 219 final). To give one example in the area of availability of healthcare professsionals: there are eight thousand times more mobile phone customers worldwide than healthcare professionals for mental health; in low-income countries the ratio is even 1 to 30000. Jones et al. show projects of successful use of m-Health applications that improves access to mental health services where healthcare professionals are scarce (Jones, Sarah P et al. (2014), *How Google's 'Ten Things We Know To Be True' could Guide the Development Of Mental Health Mobile Apps*, in Health Affairs 33; S. 1603-1611; see also: Roediger A (2015), *mHealth – on the way to health literacy 2.0* in Gesundheitskompetenz in der Schweiz – Stand und Perspektiven; 10(4); p. 77-78).

Recommendation:

- Further investigate the benefits brought by m-health and e-health.

Chapter 5: Issues related to health workforce

AmCham EU welcomes the call to put in place processes to train an adequate numbers of health workers. We believe that healthcare professionals will incresingly need to serve as mentors to patients, helping them interpret the best available information to make the best decisions about their healthcare (AmCham EU, *Forever Healthy: The 2020 Healthcare Consmer*, p.4). In this regard, we believe that new technologies will play a central role and that the health sector workforce needs to be prepared.

Recommendation:

- Include specifically the need for doctors and other health professionals to continually keep abreast of technological innovations and become more IT literate to enhance patient access to information and treatment.

Chapter 6.1: Issues related to medicines

I. Role of the pharmaceutical industry in ensuring access to health services

Over the past 60 years, healthcare innovation has played a significant role in ensuring Europeans live longer and enjoy an improved quality of life. Innovation in health has contributed to addressing challenges posed to European people by both infectious diseases and chronic conditions.

This progress would have not been achieved, without the effort of the pharmaceutical industry and its significant investments in the sector. Thanks to the efforts of the biopharmaceutical industry, survival rates for deadly disease have dramatically improved, and seriously debilitating diseases are better managed. However, the role of the industry in improving health outcomes and providing access to medicines for European patients is not sufficiently - if at all stressed in the report.

Medicines expenditure accounts for approximately 16% of total healthcare spending; focusing on the most recent ten years, retail pharmaceutical spending across the Organisation for Economic Co-operation and Development (OECD) has, on average, grown more slowly than overall health spending (OECD (2015), *Pharmaceutical expenditure and policies: Past trends and future challenges*; DELSA/HEA (2015) 6; p. 14). From 2010, in the face of reduced spending in many OECD countries, pharmaceutical expenditure turned negative with an average 2% while healthcare expenditure grew by 1.5% (see Figure 5). In addition, nominal medicine prices decreased in Europe by 16% between 2000 and 2012, in contrast to a 25% rise in consumer prices (EFPIA (2014), *Health & Growth: Working together for a healthy Europe*). The report does not provide this context but seems rather to suggest that 'the high price of many medicines is becoming an increasing problem for health systems in EU countries, threatening fiscal sustainability' (line 2,503).

There is also no analysis or evidence on access to medicines presented. In nearly all European countries, medicines – as long as they have undergone pricing and reimbursement (P&R) assessments – are covered by public health insurance, in particular so-called 'high-price medicines'. The report does not take into account recent findings of WHO, OECD and other institutions which show that the lack of access is also related to certain pricing and reimbursement policies in Europe.

Recommendations:

- Acknowledge the role of the pharmaceutical industry in improving the life expectancy of people in Europe and the quality of life of European patients.
- Put medicines in a broader context instead of singling out individual examples.

II. Research and development

The process of researching and developing new medicines is extremely long and complex. Between 1998 and 2014, there have been 123 unsuccessful attempts to develop medicines to treat Alzheimer, while only four medicines were approved (PhRMA (2015), *Researching Alzheimer's Medicines: Setbacks and Stepping Stones*). This is an example of why immense resources need to be invested before achieving success.

The pharmaceutical industry is a business and does have to make a return on investment in order to continue to exist. Very often, the best return on the investment is actually in the area of unmet needs. In 2014, for instance, 58% of new active substances approved by the United States Food and Drug

Administration (FDA) were qualified as priority reviews (CIRS (2015), 'New drug approvals in ICH countries 2005-2015', *R&D briefing 57*), meaning that they addressed unmet needs. Contrary to what is stated in lines 2,562-2,564, this figure shows that the industry is actually interested in developing new products for unmet needs rather than simply looking for high profits.

However, the average cost of bringing a drug from initial discovery to the market place is extremely high (for example, see Nature Review (2010), 'R&D productivity model and cost of drug development estimates', *Drug Discoveries, Supplementary Box S2*). The extensive and high-risk investments sustained by the industry sometimes prevents resources from being devoted elsewhere and as a result, certain medical needs remain unmet, such as in the case of antibiotics, as noted in the opinion. The lack of sufficient incentives was recognised as a cause in the rise of antimicrobial resistance (AMR) several times by the Commission, including in the Action plan against the rising threats from Antimicrobial Resistance (COM (2011) 748).

Already in 2009, the Council called for 'an urgent need to create incentives for research and development of new antibiotics, especially in those areas where the need is greatest'. Among the possible incentives, the Council specifically mentioned 'cost-effective push mechanisms to remove bottlenecks in the early stages of research and development of new antibiotics and pull mechanisms to promote the successful introduction of new products' (Council of the European Union, *Council Conclusions on innovative incentives for effective antibiotics*, 2980th Employment, Social Policy, Health and Consumer Council meeting, 1 December 2009).

While we recognise that increased efforts should be carried out to fill all medical needs, we believe that de-linkage of pricing from research and development (R&D) does not represent a solution in this regard. In fact, it may result in reduced R&D investments and thus be counterproductive in the long-term. Measures which we believe could better support innovation and should be further explored include fostering partnership among stakeholders, speeding up the production process from research to product delivery, introducing flexible and faster pathways for approval (e.g. MAPPS in the EU), providing incentives to R&D and reducing the risks of investing in health innovation.

Various concrete projects have been tested in recent years, including in the EU, which have resulted in increased access for patients as well as addressing specific medical needs. For instance, public-private partnerships (PPPs), such as the Innovative Medicines Initiative, have been successful in supporting collaborative research to advance medicines development, including in areas of unmet need (i.e. Ebola and antimicrobial resistance).

Another example is the Risk-Sharing Finance Facility (now InnovFin Infectious Diseases), which has enabled the European Investment Bank (EIB) to support innovative players active in developing products for combatting infectious diseases. Under the scheme, the EIB and the Commission share the financial risk by increasing the volume of funding available for R&D projects that aim to tackle public health needs.

Recommendations:

- Find more effective ways of funding R&D to address unmet needs, as indicated in the report's recommendations (lines 2,562-2,564).
- Remove the following sentence: 'The outcome of the current funding model has been a lack of transparency, excessive prices and a failure to develop new drugs where they are most needed' (lines 2,511-2,513), which we consider contradictory with previous EU policy documents in this field (for example, see European Commission, *Pharmaceutical Industry: A Strategic Sector for the European Economy*, Commission Staff Working Document, August 2014) and

the scientific benefit produced by the existing R&D system in terms of life-expectancy and quality of life. Furthermore, as explained in the sections below, over the last decade medicines accounted for less than 15% of the increase in healthcare spending across Europe. As a result of competition in the market and generic introduction, as well as cost containment, the average cost of medicines has declined by 16% since 2000, while consumer prices have increased by 25% (EFPIA data). Finally, industry data on aggregate R&D investments are publicly available.

- Amend lines 2,562-2,563 to recognise that in the current R&D system, innovation constitutes a risky investment. Companies look to manage that risk through viable return on investments and incentives for R&D in specific areas.
- Further reflect on the inclusion of de-linkage to address the problem of unmet medical needs as suggested in the current draft report (lines 2,513-2,514 and 2,566-2,568). In fact, like any policy that would curb the appetite to innovate, de-linking R&D from pricing may in fact have the opposite effect and affect the availability and affordability for some medicines in some countries, as recognised by the OECD (OECD (2008), *Pharmaceutical Pricing Policies in a Global Market*, p. 205).
- Include a clear call for countries to explore additional initiatives to speed up production process from research to product delivery and to provide incentives for R&D into unmet medical needs (lines 2,523-2,525, 2,566-2,567 and 2,842-2,843).
- Include a case study/box on the benefits brought by the Innovative Medicines Initiative (IMI) and other EU initiatives in fostering R&D for unmet medical needs (lines 2,579-2,580).
- Consider extended market exclusivity and inducement benefits to provide incentives to strengthen research in the antibiotic field as well as in other neglected areas (lines 2,509-2,514).

III. Authorisation

Europe has led the world in providing high standards for the authorisation and assessment of medicinal products. The EU legal framework for medicinal products for human use states that 'no medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State' (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Article 6). The same Directive clearly outlines the strict procedures to which medicinal products are subject in order to test and assess their quality, efficacy and safety before being authorised.

The EU law prohibits the promotion of medicines for unlicensed uses (Directive 2001/83/EC, art. 87) and rightly threatens companies with heavy sanctions in case of off-label promotion. However, in response to economic pressures, several health authorities across Europe have sought to either change local laws to allow economically-driven off-label use of medicines or create incentives for physicians to prescribe medicines outside of their approved regulatory license to create cost savings.

France and Italy, for instance, have recently adopted legislation that promotes off-label use of medicines for economic reasons by introducing flexible rules for the reimbursement of products for unapproved indications even when an alternative on-label product is available in their market. Such practices not only undermine patient safety, by exposing a patient to a medicine that has not been tested and approved for treatment of the patient's condition, but also puts health outcomes at risk. Promotion of economically-driven off-label use constitutes a significant disincentive for innovation by

creating market uncertainty for companies, who will be less willing to undergo the very costly and time-consuming research and development process.

AmCham EU believes it is important to monitor the correct implementation of marketing authorisations and protect the current regulatory framework, which ensures high standards for public health and patient safety. Therefore, AmCham EU is concerned by the trend in various EU member states to adopt measures that contradict or even break EU legislation in this sector with the sole purpose of achieving economic savings.

With regard to the perceived conflict of interest between the pharmaceutical industry and the European Medicines Agency, we would like to reiterate that the pharmaceutical industry's primary obligation remains to ensure that the medicines it produces benefit society. Industry's financial contribution to the European Medicines Agency (EMA) is limited to the market authorisation services it provides, as is the case with licensing in any industry.

There is no evidence that the funding in any way influences decision making. The EMA itself only provides an administrative secretariat that coordinates activities, collects fees and carries out administrative tasks. It is the Committee for Medicinal Products for Human Use (CHMP), which is composed of regulators from member states competent authorities, that makes the marketing authorisation recommendations. It is hard to see how payment of fees would influence a Committee for Medicinal Products for Human Use (CHMP) decision. Furthermore, the CHMP opinions are subject to peer review by every member state regulatory authority before the final marketing authorisation decision is made by the Commission.

Recommendations:

- Include a reference on the importance of monitoring and protecting the implementation of the existing regulatory framework to safeguard high standards for public health and patient safety (lines 2,575-2,576).
- Underline the importance of ensuring the respect of EU legislation on medicines authorization and highlight the risk to patient safety of promoting the use of drugs outside of their approved use and/or dose.
- Take account of economically-driven off-label use and recommend that such practices stop in the EU.
- Delete the paragraph on EMA fees as it does not relate to access and lacks any reference to substantiate such a claim. Otherwise, authors should reach out to EMA for their opinion or at least add to the information currently provided by specifying that the industry contributes to the EMA solely in for the services it provides and that the decision on marketing authorisation is taken transparently and independently (lines 2,578-2,579 and 2,837-2,840).

IV. Pricing

Various researches shows that medicines are not the main drivers of rising healthcare costs; rather, spending on medicines has risen far more slowly than overall healthcare spending, and spending on medicines as a percentage of GDP has actually fallen in Europe. Medicines expenditure accounts for approximately 16% of total healthcare spending; focusing on the most recent ten years, retail pharmaceutical spending across the OECD has, on average, grown more slowly than overall health spending (OECD (2015), *Pharmaceutical expenditure and policies: Past trends and future challenges*; DELSA/HEA (2015) 6; p. 14).

As it stands, the opinion fails to recognise that innovative medicines transform health systems, the way they treat numerous diseases and how these diseases affect the lives of patients, their families, and care givers across Europe. For example, innovative medicines reduced in the death rate from HIV/AIDS by 83% and that from cancer by 20% (with five year survival rates climbing to 68%). There was also an increase of cure rates for Hepatitis C by 90% (PhRMA (2015), *Profile: Biopharmaceutical Research Industry*).

Another example is the cost of cancer medicines, which have often been blamed as one of the main challenges to the sustainability of cancer care systems. In fact, cancer medicines make up a small portion of the overall healthcare spending and drive progress in the advancement of oncology medicines, which may eventually help prevent other, more costly, interventions such as hospitalisations. It is important to consider that in the EU, drug expenditure in 2009 accounted for 27% of all cancer-related healthcare costs. In comparison, inpatient care costs accounted for 56% of cancer-related healthcare costs (R. Luengo-Fernandez *et al*. (2013), 'Economic burden of cancer across the European Union: a population-based cost analysis', *Lancet Oncol*. 2013 Nov, 14(12), pages 1,165-74).

The section also fails to acknowledge the fact that every EU member state has price controls and well established price review systems as well as the power to block access to reimbursement of the new product if the price is considered to be too high.

Medicines' prices are based on the value brought to patients, providers, payers and society. Value may come from the following areas: device and delivery system, the incremental benefit of a comparator versus no comparator, patient preference, improvement in quality of life, healthcare system savings, care within or outside hospital, work days gained and the extent to which it advances treatment or targets patient populations. In areas where treatments exist, companies and governments examine the value of a medicine versus that of alternative innovative treatments within that therapy area. This includes considerations on additional efficacy, improved safety, and reduction of other healthcare costs, increased productivity or other benefits to the patient and the country versus that of the existing standard of care. In areas where there are no existing treatments or standard of care, value created by a new medicine is assessed relative to other medical innovations that offered similar value in similar therapeutic areas.

With regard to External Reference Pricing (ERP) the WHO report on Access to Medicines in Europe gives interesting background on potential access issues resulting from this policy: 'While ERP may help contain costs by reducing prices, critics are concerned about arbitration of the targeting price, launch delays and the lack of incentives for innovation. Sweden, the United Kingdom and – until recently – Germany are characterized by relatively free pricing mechanisms for pharmaceuticals. This, coupled with their strong local pharmaceutical industries, has often led them to be the first to adopt pharmaceutical innovation, although there have been concerns with the rate of adoption of new medicines in the United Kingdom, including new cancer medicines. Further, in order to hinder low-price spillover through ERP, products are often launched in higher-priced EU markets, which can lead to launch delays and high launch prices in lower-priced EU markets such as Portugal and Spain or no launch at all in less wealthy countries' (WHO Europe (2015), *Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research*; p. 60).

The issue of access delays has been investigated by Glynn and shows that lower income Eastern and Southern European countries tend to face longer delays than their Western and Northern European counterparts. At the extremes, Portugal had to wait an average of 46 months for new oncology drugs after they were released elsewhere in Europe. Switzerland (not an EU member) and the Netherlands

had to wait just 5 months. For diabetes drugs, Croatia had the longest delay at 37 months, while Switzerland again had to shortest delay of just one month and five wealthy EU Member States waited only about two months (Glynn D (2013), *External Reference Pricing,* Europe Economics). While reasons for the lack of access are manifold, the report assessed access to medicines only in a narrow way.

AmCham EU believes that the ability to charge different prices in different European countries is essential for making medicines affordable to health systems in every country. Differential pricing, paired with programs such as targeted programs for low and middle-income countries, and patient assistance programs, allow companies to work with relevant authorities to enhance patient access for medicines. On the other hand, reference pricing and a uniform European price could lead to an increase in inequality of access without taking into account the actual ability of a country to pay. Converging towards an average price could lead to inevitably higher prices in poorer countries.

AmCham EU believes that without patents, many of the existing drugs would not have been produced and innovative medicines, for instance the ones needed to fight antimicrobial resistance, would not be developed. Patents perform an essential role in stimulating the development of essential drugs by offering incentives for investing in expensive and long-term research for the development of new drugs (United Nations World Intellectual Property Organisation (WIPO), *Striking a balance: The patent system and access to drugs and healthcare*, 2009).

According to the United Nations (UN) World Intellectual Property Organisation, patents are only one of many factors that influence access to health care and drugs and patents are not necessarily the determining factor in the price of drugs. In fact, 95% of the pharmaceutical products on the WHO's Essential Drug List are now 'off patent'. Yet many of these 'off patent' drugs remain unavailable or unaffordable (WIPO, *Striking a balance: The patent system and access to drugs and healthcare*, 2009).

Recommendations:

- Remove the sentence about the US physicians (lines 2,586-2,588) as their petition relates to the US pricing of oncology drugs and patient co-payments which is not relevant in the EU context.
- Carefully consider the reference to a maximum price at EU level (lines 2,632-2,634) and to 'reference pricing' (line 2,641) as tools to increase affordability. We believe forcing pricing in Europe into a narrower range would easily result in increased prices in the poorest countries, making affordability a bigger problem and increasing inequalities at EU level. Reference pricing may not only result in higher prices in lower-income EU countries, but may also bring delayed entry of products in low-paying countries in an effort to avoid a drop in prices in the high-paying countries.
- Recognise that the price of drugs depends on a wide variety of factors, including the cost of research and development, production, distribution and marketing, and does not represent the main driver of rising healthcare costs (lines 2,590-2,591).
- Guarantee the integrity of the patent protection system for healthcare products, including the Supplementary Protection Certificate (SPC). The opinion should also acknowledge the key role that the patent system has played in fostering innovation in healthcare, as in other key sectors, by providing the adequate incentives for the industry to support high-risk investments (lines 2,598-2,601).
- Avoid making recommendations on pricing mechanisms given the complexity of pricing and reimbursement and instead make supportive recommendations to ongoing EU activities that are reviewing pricing mechanisms in detail. It should be acknowledged that this is a complex

issue where a pricing resolution needs to deliver new medicines that improve health outcomes while balancing healthcare system sustainability and a health innovative pharmaceutical industry.
- Remove the paragraph stating that 'if companies ask for the highest prices the client is willing to pay, then patent protection should be removed' (lines 2,608-2,615), taking into consideration the arguments explained above with regard to price negotiations and the value of a drug.

V. Procurement

AmCham EU agrees that if joint procurement of medicines results in a single price throughout Europe, medicines risk becoming unaffordable in some EU Member States. Please see chapter on pricing for more details.

Recommendations:
- Continue to have procurement dealt with at member state level - with the exception of serious cross-border health threats - allowing for price differences between countries. This situation enables an adaption of the price level to the country-specific purchasing power and ensures access for patients and affordability (lines 2,653-2,659 and 2,835).
- Ensure that procurement by tendering allows health services to make the best decisions for patients and for health systems. Price might not always be the most meaningful award criteria. An optimal price-quality ratio rewarding valuable innovation should be ensured.

VI. Coverage

AmCham EU welcomes the focus on a more careful assessment of reimbursable medicines to eventually ensure financial protection. Value assessments in EU Member States have often proved to be too narrow, only focusing on the impact of new medicines on the national pharmaceutical budgets. In addition, the current patchwork of valuation and assessment criteria across Europe is leading to a wasteful duplication of efforts in both public and private sectors. Differences in applying Health Technology Assessments (HTA) pose challenges for industry, patients and healthcare systems.

Recommendation:
- Call for increased consistency among HTA approaches in EU Member States in order to prevent delays in patients accessing new medicines (line 2,678).

VII. Prescribing

We note that existing legislations and inconsistencies among different national models with regard to non-prescription medicines result in inequalities in their access within different EU countries. A centralised decision on the switch of a centrally-authorised medicine to non-prescription status remains extremely difficult to reach. In ten years, only six so-called 'switch' applications have been made, of which three have been successful (AmCham EU, Letter to Malcolm Harbour, *The Single Market: a work in progress*, 2013).
3).

Recommendation:

- Call for a clarification of the current legislation to ensure that prior central authorisation does not prevent non-prescription status by national boards of health.

VIII. Antibiotics (Box 6.1)

AmCham EU agrees that there is currently little market interest for developing new antibiotics. The current reimbursement environment for antibiotics is recognised as a problem and there are already work programmes at the EU and US levels (e.g. GAIN) to address this. This is becoming an issue of increasing concern, especially considering the rise in resistance to existing drugs. While the solution to the problem cannot only come from further innovation, we believe that the paper fails to provide solutions to tackle the issue from an R&D point of view.

For a business to develop a medicine there has to be a positive return on investment. In the US, for instance, an FDA act providing companies with five more years of exclusivity without generic competition resulted in increased investments in the area. Inducement prizes have also proved their potential in catalysing resources for unexpected research. Other incentives can be research credits or public/private partnership, such as IMI which has also launched projects on antimicrobial resistance (AMR). In this regard, the Council of the EU called for 'cost-effective push mechanisms to remove bottlenecks in the early stages of research and development of new antibiotics and pull mechanisms to promote the successful introduction of new products' (*Council Conclusions on innovative incentives for effective antibiotics*).

At present the PEW Charitable Trusts – who tracks the development of antibiotics – report that as of 28 July 2015, there are 36 new antibiotics in development with eight in phase I, 20 in phase II and eight in phase III and of these 16 could address infections causes by pathogens considered an 'urgent threat' to public health (The Pew Charitable Trusts, *Tracking the Pipeline of Antibiotics in Developmen*t, Issue Briefing, 28 July 2015).

Recommendations:

- Consider inserting references to extended market exclusivity, research credits, public-private partnership and inducement prizes to provide incentives to strengthen research in the antibiotic field as well as in other neglected areas (lines 2,509-2,514).

IX. Macular degeneration (Box 6.2)

The EU legal framework for medicinal products for human use states that 'no medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State' (Directive 2001/83/EC, art. 6). The Directive clearly outlines the strict procedures to which medicinal products are subject in order to test and assess their quality, efficacy and safety before being authorised.

The EU legislation in this sector is intended to ensure a high level of public health protection and to promote the functioning of the internal market. While we understand the complexity of the mentioned case, we believe that the protection of the existing legal framework at EU level is paramount to ensure patients' safety when accessing healthcare. AmCham EU is concerned by the trend in various EU member states to adopt measures that contradict or even break EU legislation in this sector with the sole purpose of achieving economic savings.

Recommendation:

- Underline the importance of ensuring the respect of EU legislation on medicines authorisation and highlight the risk to patient safety of promoting the use of drugs outside of their approved indication and/or dose (box 6.2).

X. Hepatitis C (Box 6.3)

Innovative drugs can command a high price. This is mainly due to the complexity of the R&D process, not least the cost of running large, often complex clinical trials. Various studies have demonstrated that, while Sofosbuvir is expensive compared to traditional treatment for Hepatitis C, it costs much less than having a patient undergo a liver transplant, which causes high levels of trauma for the patient which would be better treated through long-term, intensive care.

Sovaldi is not priced significantly more than the comparators despite being a cure and therefore offering an advantage. The real problem was not cost-effectiveness but a combination of time and patient numbers. A course of the comparator Hepatitis C drug was around 48 months compared to 12 weeks for Sovaldi, meaning that the full cost of Sovaldi hit the healthcare system within a single year. In addition to this, the sheer number of patients would impact budgets of healthcare systems that separate their healthcare expenditure into silos. The drug was shown to be cost effective (for instance by the National Institute for Health and Care Excellence (NICE) and would represent a very good long term investment for the healthcare system. Research from the PwC Health Research Institute suggests that the cost of curing Hepatitis C with Sofosbuvir would indeed increase healthcare costs in the immediate future, but the amount of spending on Hepatitis C would decline within a decade thanks to savings in other healthcare expenses (PwC, *Medical Cost Trend: Behind the Numbers 2015*, June 2014).

Recommendation:

- Acknowledge the long-term effect of breakthrough innovation in improving quality of life of patients and realising savings for the healthcare system.

Chapter 6.2: Issues related to medical devices

Medical technology is responsible for increasing life expectancy in many disease areas, improving the quality of life of individuals with chronic medical conditions and allowing them to remain integrated, valued and productive members of society.

In recent years, the medical devices industry has made significant progress in developing innovative solutions for patients. With over 500,000 medical devices currently available in the European market, patients have also become increasingly reliant on these products and expect the highest safety standards from them (MedTech Europe, *The European Medical Technology Industry in Figures*, 2010).

The industry has enabled dramatic advances in how chronic conditions such as cardiovascular disease and diabetes are managed. In addition, individuals who undergo surgical procedures now benefit from improved techniques. Minimally invasive procedures, which have been made possible by medical technology, offer patients highly reduced treatment and recovery times with less risk of complications, allowing them to return to a productive life more quickly.

Medical technology has also facilitated increased use of community care, allowing treatment to be delivered at, or close to the individual's home. For those with chronic conditions, there are considerable benefits in not having to travel to a hospital for routine healthcare.

While it currently represents less than 5% of healthcare budget spending, the medical technology industry is constantly scrutinised and pushed to deliver better outcomes in a more cost-effective way (Eucomed 2011, *Contract for a Healthy Future*). AmCham EU is concerned by a number of cost cutting mechanisms that, if carried out, would threaten the medical devices industry and could be damaging to the patient community.

I. Reprocessing

The opinion states that the process of reprocessing and re-using medical devices designed for single use merits attention. Furthermore, it states that the economic crisis creates opportunities for countries to negotiate better prices, to organise joint procurements schemes and to assess the rate at which they prescribe devices (lines 2,899-2,900).

Over the years, single use medical devices (SUD) have been re-processed by hospitals and clinicians to save costs and reduce environmental waste. While we recognise the increasing economic pressure healthcare systems are under, we believe there are important health risks associated with reprocessing SUDs that cannot be ignored.

Ensuring the traceability of the device is an important part of the manufacturing process that the re-processor is responsible for. Without a clear tracking system, it becomes difficult to effectively report and learn from device failure.

If a SUD is to be reprocessed effectively, there must be strict safety protocols in place at each step of the process, from cleaning to labelling. It could be a challenge for the re-processer to know what protocols to set, especially when they have had no guidance or safety instructions from the original manufacturer.

Furthermore, it should be noted that the European Parliament recently stated 'The current possibility to reprocess medical devices labelled as single-use is not acceptable from a safety point of view' (European Parliament Amendment 358 to the proposal for a regulation of the European Parliament and of the Council on medical devices, P7_TA(2013)0428).

Finally, the European Commission itself has recently argued that there is limited 'scientific evidence and economic evaluation to demonstrate that the reprocessing of single use medical devices is globally a cost effective practice' (European Commission, *Report on the issue of the reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC*, COM/2010/0443).

Recommendation:

- Avoid sanctioning the reprocessing of single use medical devices for economic reasons;
- Implement strict protocols legally binding to ensure a high standard of patient protection in Europe.

II. Rational use

We would like to underline that medical technology contributed to a 13% reduction in the average length of hospital stay between 2000 and 2008, cutting costs dramatically. This can be attributed to new, innovative products for surgical procedures, such as knee and hip replacements. In the case of cataract surgery, the vast majority of procedures are now performed without any need for an in-patient stay. The use of e-health solutions such as telemonitoring, as well as the shift from hospital to community care, also contributes to reducing overall care costs. There are other benefits, too, such as improved patient safety with the appropriate use of medical devices designed to minimise the risk of adverse events and complications whilst maintaining high quality of care.

Recommendations:

- Acknowledge that the cost effectiveness assessment not only threatens the medical device companies' business model but it also poses a threat to patient safety. It could mean that some patients may not get the necessary equipment or care due to greater rationalisation. It also puts additional pressure of physicians to consider the economics of prescribing devices when they should be focussed on health outcomes.
- When making reimbursement decisions, specify that evaluating medical technology should always consider the savings that better patient outcomes can bring to the healthcare systems (lines 2,792-2,793).

III. Other areas related to medical devices

We welcome the recommendation on reinforcing the capacity of EUnetHTA (line 2,988) since we believe that joint HTA methodologies will increase efficiencies, reduce duplications and increase access for patients.
We welcome the report's call to promote R&D in medical devices and optimal utilisation strategies (line 3,001).

Other areas: Issues related to EU and Member states responsibilities in ensuring equitable access

Recommendations:

- Include a call for action to the Commission, in conjunction with the Council of Health Ministers, to develop a pan-European platform to exchange information, expertise and best practices on data surveillance and analysis of health and epidemic trends of the European population in order to infom the development of effective policy frameworks (page 109).
- Call the Commission and the Parliament to drive and adopt new data protection rules and regulations so as to enable appropriate use of data to inform health intervention strategies, while ensuring that patient privacy is protected (page 109).