AmCham EU position on the European Commission Staff Working Document *Pharmaceutical Industry: A Strategic Sector for the European Economy*

The Health Sector – Key Driver for Europe's Growth andCompetitiveness Agenda

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the European Commission Staff Working Document (SWD) *Pharmaceutical Industry: A Strategic Sector for the European Economy*. The SWD presents a valuable assessment of the sector. The pharmaceutical sector is a major driver of the Innovation Union, investing more than any other sector in research and development (R&D), creating directly and indirectly highly-skilled jobs and strengthening Europe's competitiveness in a global market.

As highlighted in the Commission's document, key challenges for the pharmaceutical industry are demographic change, financial constraints of national budgets and increasing competition from outside the EU. To address these challenges, AmCham EU proposes establishing a multi-stakeholder platform to identify inefficiencies in regulations and policies.

Recent developments in the health industry such as personalized medicine, data analytics, eHealth/mHealth, or services suggest that the delivery of healthcare has to become more integrated, in order to be more efficient, more effective and more productive. Hence, we recommend that the European Commission considers taking a broad approach towards a comprehensive life sciences strategy.

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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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Introduction

The Commission Staff Working Document (SWD) *Pharmaceutical Industry: A Strategic Sector for the European Economy* [1]provides a valuable assessment of the sector, its environment and the various initiatives of the European Commission. The sector is indeed the most R&D (research and development) intense sector with a global ratio of 14.4% of investment in R&D compared to sales, and has the second largest R&D intensity in the EU (13.9%).[2] In Europe alone, the research-based pharmaceutical industry invests around €30 billion in R&D each year.[3] It directly employs 700,000 people and generates three to four times that number of indirect jobs. At a country level, for every job created in the Czech pharmaceutical sector, for example, in 2009, 5.8 jobs were created elsewhere in the economy.[4]

Industry's research and development activities such as clinical trials provide a number of tangible and intangible contributions to society and the economy. As a report on Poland found out, clinical trials provide access to advanced therapies for patients, combined with better standards of medical care; contribute to human capital growth in terms of know-how, knowledge sharing and professional development opportunities for medical staff.[5] In addition, clinical trials contribute to the Polish economy with c. PLN 860million (approx. €203million) of which the vast majority is a cash inflow and the state budget with c. PLN 240million (approx. €57million) of taxes. Finally, the R&D-based pharmaceutical industry contributes significantly to Europe's trade surplus, estimated to have reached €80 billion in 2012 alone.[6] Taking the sector and the wider eco-system nourished by the sector, life sciences represent a key asset for the European Union to achieve the EU 2020 goals of smart, sustainable and inclusive growth.[7]

However, the sector has come under significant pressure and faces a number of uncertainties. During the crisis, health spending had stagnated or even fallen for the first time.[8] Health expenditure only started to rise again in 2014, but the pace of growth remained well below pre-crisis rates, especially in Europe, according to OECD Health Statistics 2014.[9] Pharmaceutical spending continued to decrease in almost two-thirds of OECD countries.[10] We therefore agree with the Commission's assessment that 'Europe's pharmaceutical sector suffers from a lack of confidence, market uncertainty and budgetary problems which are currently preventing it from developing its full potential.'(SWD, p.3)

Against this backdrop, AmCham EU welcomes the European Commission's objective to strive for a strategic agenda for the pharmaceutical sector as mentioned in the Commission Industrial Policy Communication Update.[11] In particular, as the role of health and the healthcare sector were only partly reflected in the EU 2020 Strategy and in the Commission's Communication on an 'Integrated Industrial Policy'.[12]

In addition to the footprint of the pharmaceutical industry, healthcare as such plays a particular role in all industries, as its output is essential for any industrial base. In the context of the Lisbon Strategy in 2005, McKee and Suhrcke found that, 'the evidence […] provides compelling confirmation that judicious investment in better health in the high income countries of Europe can be expected to increase productivity and increase labour supply.'[13] Innovation in the pharmaceutical sector has strongly contributed to improve productivity as shown for the improvement in functioning and productivity due to new drugs for Arthritis.[14] Other studies for example found that pharmaceutical innovation contributed significantly to the increase in German life expectancy and to welfare gains in the Netherlands.[15] Therefore, health is fundamental for any industry as it is the basis for productivity and growth; the healthcare sector has a specific role to play in the industrial context.

Issues

AmCham EU has been working for a long time on a variety of topics relating to industrial policy such as the value of health, investment in health care and future health.[16] Thanks to the cross-functional approach of the Healthcare Committee, including the pharmaceutical, medical device, eHealth/mHealth, food, transport and other sectors, AmCham EU was able to respond from a more holistic healthcare perspective.

The pharmaceutical industry as a sector is highly regulated. As a consequence the pharmaceutical business model depends to a great extent on the policy environment as it is provided by Member States, payers, and the European Commission. Medicinal products undergo rigorous assessments through the Marketing Authorisation Process before they can be placed on the market. Once on the market, medicines are procured by governments or health insurers. Prices and reimbursement of medicines are regulated by Member States and payers, through a different process in each Member State and often include different data requirements, comparators and timelines. Taking into account that the research and development of new medicines takes usually 12 to 13 years with an investment of approximately more than €1.1billion per new chemical or biological entity[17] the impact of policy changes might only be seen years later. Such policies represent strong – positive or negative – signals to the industry in respect of investment and innovation.

Therefore, a strategic agenda for the sector that aims to achieve the overarching goals of the European Union (EU) needs to take into account the regulatory requirements and the subsequent demand-side policies. In fact, most of the issues and challenges have been adequately identified by the Commission Staff Working Document; AmCham EU would therefore like to highlight only a few specific issues that deserve further consideration:

- *Making policies that unlock innovation*

  Medicines have many values. There are primary medical benefits such as lowering pain and physical markers, e.g. delaying the onset or deterioration of a strongly symptomatic disease

such as Alzheimer's, all of them contributing to better health. Furthermore, there are other factors such as better tolerability, less interaction with other drugs and improvements of the patients' quality of life; 'The value of any one medicine, or class of medicines, comes from demonstrating the benefit to the patient, carer, payer, prescriber and society as a whole.'[18] Improving adherence – that may improve efficiency in healthcare resource use – or accelerating workability which increases productivity are benefits that also need to be captured in the assessment of value.

Health Technology Assessment (HTA) is another instrument that has an impact on innovation. HTA processes can support rational decision making about coverage and maintenance of medicines provided that they take into account the value and impact of new medicines for the whole healthcare system, as well as their socio-economic benefits. Unfortunately, value assessments in the Member States are often 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 HTA pose challenges for industry, patients and healthcare systems. We agree with the following statement on SWD, p.17: 'Although HTA has been proven to be a valid tool for addressing cost-effectiveness issues, approaches to HTA across Member States differ considerably. Diverging requirements between Member States can lead to shortcomings in the efficient allocation of resources, thus possibly to higher costs for competent authorities and industry and most importantly to delays in access to new medicines for patients.' In comparison to the harmonised international regulatory requirements, HTA requirements, processes and methodologies are highly diverse which create uncertainty, unpredictability and often lead to a mix of outcomes based on the same input data.

Finally, besides the value assessment other means in the area of procurement can have an impact on innovation as well: many tenders focus only on price forgoing longer-term benefits, which in the end may have a major budget impact. In addition, certain forms of tenders may reduce the number of suppliers, which in the long run may lead to shortages and undermine competition – which in turn is a key factor for efficiency. We therefore agree with the Commission's call for 'taking into account the effects on other health-related costs' and hence a 'more integrated approach,' (SWD, p.9).

- *Ensuring consistency between policies*

The Treaty gives Member States full responsibility in managing and financing healthcare provision.[19] However, the impact of national policies is often not limited to the respective Member States. One issue in the context of policy consistency is the interplay between industrial policy and competition policy: in recent years, the interference of anti-trust law with the acquisition, exercise or enforcement of intellectual property rights (IPRs such as patents, SPCs, etc.) has reached an unprecedented level. IPRs are of fundamental importance for an

innovation-driven health sector in Europe. While competition law and policy are of course important pillars of the Single Market, it seems that the time has come to reconsider the way in which competition applies or should apply to IPRs.

In the area of pricing and reimbursement External Reference Pricing (ERP) is an example of conflicting policies. Through ERP, Member States determine prices of medicines based on a comparison of prices in other Member States. At a second level it creates strong and often unintended links between policies of different Member States. If a Member State decides to cut prices of certain products, the ERP mechanism creates spillovers to other jurisdictions to the extent that nationally designed policies gain a regional impact. This, on the one hand, creates unpredictability for the pharmaceutical sector which operates globally. On the other hand, it can lead to situations where pharmaceutical companies delay the launch of products or refrain from markets, exacerbated by parallel trade – which in the end has an impact on patient access and affordability of medicines in lower-income European countries.[20,21] AmCham EU supports the Commission's view that there is a need to tackle 'shortcomings in the coordination between the policy objectives and subsequent effects of national decisions in other Member States,' (SWD, p.10).

- *Improving efficiency in healthcare systems*

The Staff Working Document rightly points out the growing challenge of 'finding a balance between the emergences of new and often more costly pharmaceutical therapies and the legitimate expectation of patients to get access to innovative and effective medicines, on the one hand, and the need to ensure sustainable public healthcare budgets on the other hand (SWD, p.6). While pharmaceutical expenditure constitutes on average only 15.1% of Member States' healthcare bill[22], governments tend to cut pharmaceutical spending as an easy target to achieve short-term savings. The SWD recommended containment of future growth in medical expenditures, notably for medicines, risks being too narrowly focusing on one element of the overall healthcare expenditure instead of overall efficiency gains and compromising Europe's long-term health outcomes, productivity and employment. Additionally, as some Member States seek economies at any costs, e.g. through promotion of economic-driven off-label use of medicines, patient safety in Europe may be compromised.[23] A more holistic value assessment which includes also indirect benefits, such as productivity gains, will lead to integrated management of health and social care, and to the breaking down of budget silos which may contribute to the efficiency of healthcare systems.

- *Promoting European regulatory standard*s

Europe has been a leading region in providing standards for the assessment of medicinal products. The European Medicines Agency (EMA) was the first body to issue guidelines on biosimilars. The World Health Organization (WHO) and countries including Canada, Australia and South Africa have followed the EMA's lead soon after and adopted similar

principles in their guidelines to regulate Marketing Authorisation for biosimilars.[24] Such regulatory standards are sometimes questioned or even lowered in other regions which could not only lead to different regulatory standards for patients but also undermines the competitiveness of the European industry.

Standards play also an important role in trade agreements. AmCham EU invites the European Commission to include in its agenda for the pharmaceutical industry a focus on enhancing the industry's competitiveness and eliminating barriers for it to compete at a global scale. One important short-term step in this direction is a comprehensive and ambitious free trade agreement between the EU and the US, namely the Transatlantic Trade and Investment Partnership (TTIP). TTIP should aim to promote regulatory compatibility, strengthen intellectual property protection, and enhance patient access to innovative biopharmaceuticals. In addition, many of these elements, such as regulatory compatibility, can be expected to not only benefit bigger companies, but have a particularly positive impact on smaller companies and collaborations that are central to the broader life sciences ecosystem. We strongly believe that all these elements will help accelerate global development of medicines and enhance patient access to much-needed innovative medicines.

- *Working towards a life sciences strategy*

Further progress in our understanding of disease through advanced computing, sensing, molecularbiology, connectivity, and 'big data' analytics will frame the future use of pharmaceuticals. In this light, there are many policy issues that can affect how far we would be able to harness the potential of pharmaceuticals. If the EU is to capture the economic promise of the pharmaceutical sector, we need to understand the much broader policy environment, which of course encompasses many issues that can enhance, challenge or in some cases prevent the development of this sector. Personalised medicine will lead to a closer link between diagnostics, medicines, devices, and eHealth/mHealth. However, as noted in the '-omics' report 'while medicinal products and the screening of genomic characteristics with diagnostic tests are closely inter-linked in personalised medicine, the current EU regulatory frameworks for the marketing of medicinal products and the corresponding diagnostic medical devices are different.'[25] More and more medicinal products are also linked to certain services such as mobile applications and adherence support programmes. Finally, the EU data protection framework plays a key role in making sure that health data can be used for improving treatments and care in a patient-centric way. While there are good reasons for this diversity and complexity, a comprehensive life sciences strategy must ensure that the different regulatory frameworks do not hinder the potential of pharmaceuticals and healthcare to become more personalised.

As future initiatives for the pharmaceutical industry are considered all elements of the value chain need to be reflected. AmCham EU encourages the European Commission also to remain cognizant of the importance of healthcare logistics as an enabler of affordable

pharmaceuticals, and efficient storage and delivery of pharmaceutical products for hospitals, pharmacies, businesses and individual consumers across the European Union. A closer cooperation between the pharmaceutical industry, medical devices, eHealth/mHealth services and other sectors can be expected which changes the setup of the sector. This needs to be reflected and may require a more comprehensive strategic agenda addressing the whole life sciences sector.[26]

The way forward

In its position paper *Investment in Healthcare*, AmCham EU has identified a number of areas that are still relevant for industrial policy including[27]:

- Safeguarding innovation in the long run by implementing policies that overcome static thinking and unleash dynamic efficiency;
- Providing smart regulations that are limited to their purpose; and
- Supporting innovative partnerships between the public and private sectors.[28]

In addition, in its publication *Forever Healthy.The Healthcare Consumer 2020*, AmCham EU called for 'investing in innovation that can drive efficiencies, improve productivity and facilitate patient-centric care'.[29]

AmCham EU concurs with the assessment of the Commission that 'a comprehensive approach helping to streamline the policy formulation process at European and Member State level could facilitate future decisions' (SWD, p.25). Since industry belongs to the wider part of society, any industrial policy has to be developed in the context of wider goals of the European Union such as a smart, sustainable and inclusive growth.[30]

Health as such is in the middle of the 'stress field' of economy, wealth and budget: health is an important economic sector, representing 10% of GDP and 8% of employment, it also contributes to productivity and growth; but, as part of the social system it has also a major impact on national budgets.[31] A similar 'trilemma' can be seen in terms of pharmaceutical policy, as pointed out by the OECD: 'Beyond this, the pharmaceutical industry plays an important role in the economy of several OECD countries. These varying conditions are likely to influence the relative weight policy makers apply to common policy goals such as access to effective treatments, cost containment and value, and; how they seek to resolve conflicts that may arise among these goals and with industrial policy goals.'[32] In a situation of conflicting goals, balance is the only viable approach, i.e. a balance between clear incentives for future innovation, access to health and maintaining the sustainability of healthcare systems.

Therefore, AmCham EU recommends continuing with the multi-stakeholder approach, in two areas:

- Further assess the role of the life sciences industry in the wider industrial policy through an impact assessment ('footprint') i.e.
    - Assess the impact of the life sciences industry on the EU's growth and competitiveness in the context of the EU2020 goals and in relation to other sectors (footprint); and
    - Explore a wider life sciences industry policy approach which includes also other healthcare industries such as medical devices and eHealth/mHealth.

- Identify areas for smarter regulation and provide a platform to resolve conflicts of policies:
    - Establish a similar multi-stakeholder platform approach as the Platform on Access to Medicines[33] in Europe to identify inefficiencies in regulations and policies with a clear focus on fostering innovation, access and affordability;
    - This includes establishing a collaborative approach towards improving the predictability of the HTA, reimbursement and patient access environment in the EU Member States through sharing best practices and identifying workable principles, but also trade agreements such as TTIP; and
    - Based on the platform's results provide concrete proposals for smarter regulation and ensure close cooperation between the different Directorates General.

References

[1]European Commission (2014), Commission Staff Working Document.Pharmaceutical Industry: A Strategic Sector for the European Economy; SWD (2014) 216 final
[2]European Commission (2013), The 2013 EU Industrial R&D Investment Scoreboard; p. 45
[3] EFPIA – European Federation of Pharmaceutical Industry and Associations (2013): The pharmaceutical Industry in Figures: Key Data (2013)
[4]EFPIA (2013), Health & Growth - Evidence Compendium; p. 143(accessed: 18/09/2014)
[5]PricewaterhouseCoopers (2010), Clinical Trials in Poland – Key Challenges; (accessed: 20/10/2014)
[6]EFPIA – European Federation of Pharmaceutical Industry and Associations (2013): The pharmaceutical Industry in Figures: Key Data (2013)
[7]European Commission (2010), An Integrated Industrial Policy for the Globalisation Era. Putting Competitiveness and Sustainability at Centre Stage; COM(2010) 614, p. 26
[8]Morgan D, Astolfi R (2014), Health Spending Continues to Stagnate in Many OECD Countries; OECD Health Working Papers No. 68, p. 4: "Estimates of expenditure on health released back in 2012 showed that, for the first time, health spending had slowed markedly or fallen across many OECD countries after years of continuous growth."
[9]OECD (30/06/2014), Health spending starts to rise but remains weak in Europe, says OECD;
(accessed: 18/09/2014)
[10]Ibid: 'While spending on hospital and outpatient care grew in many countries in 2012, almost two-thirds of OECD countries have experienced real falls in pharmaceutical spending since 2009.'
[11]European Commission (2012), Stronger European Industry for Growth and Economic Recovery. Industrial Policy Communication Update; COM(2012) 582 final, p. 17
[12]European Commission (2010), Europe 2020. A strategy for smart, sustainable and inclusive growth; COM(2010) 2020; European Commission (2010), An Integrated Industrial Policy for the Globalisation Era
Putting Competitiveness and Sustainability at Centre Stage; COM (2010) 614, p. 26.
[13] McKee M, Suhrcke M (2010), Investing in Health: A Contribution to the Achievement of the Lisbon Agenda; European Review, 18:1, 17
[14]EFPIA (2013), Health & Growth - Evidence Compendium; p. 35(accessed: 18/09/2014)
[15]Lichtenberg F (2010), The Contribution of Pharmaceutical Innovation toLongevity Growth in Germany and France; CESIFO WORKING PAPER NO. 3095; Tsiachristas A, Goudriaan R, Groot W (2013), The welfare effects of innovative pharmaceuticals: an international perspective from the Dutch experience; Applied Economics 45:1219-1226
[16]AmCham EU (2012), Investment in Healthcare; (accessed: 17/09/2014)
Forever Healthy. The Healthcare Consumer 2020; (accessed: 17/09/2014)
[17]EFPIA (2014), The Pharmaceutical Industry in Figures. Key Data 2014; p. 6
[18]Ibid p. 7
[19]Official Journal (9.5.2008), Consolidated Version of the Treaty on the Functioning of the European Union; Article 168(7)
[20] Glynn D (2013), External Reference Pricing;
http://www.europe-economics.com/publications/15/publications.htm (accessed: 18/09/2014)
[21]GIRP (2013), Medicine shortages in Europe and their impact on patients – a reflection paper;
http://www.girp.eu/sites/default/files/documents/Medicines%20shortages%20reflection%20paper%20including%20exec.%20summary%20FINAL.pdf (accessed: 18/09/2014).
Various companies decided not to launch their products after a negative decision on their product in Germany. While not always mentioned explicitly, one of the reasons is the potential impact on other markets since Germany is one of the most referenced markets. See APM (22/02/2013), German pharma lobby backs Boehringer, disputes G-BA negative decision on Trajenta; APM (14/04/2014), BRIEF: Almirall to withdraw irritable bowel syndrome drug Constella from the German market
[22] EFPIA Health & Growth project data.
[23] 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. Please see also the EFPIA position on the topic:
http://www.efpia.eu/uploads/EFPIA_Position_Paper_Off_Label_Use_May_2014.pdf
[24]McKinsey&Company (2013), Biosimilars seven years on: Where are we and what's next? Insights into Pharmaceuticals and Medical Products; p. 1
[25]European Commission (2013), Use of '-omics' technologies in the development of personalised medicine; SWD(2013) 436 final; p. 16
[26]http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture-Life-Sciences-Overview.pdf
[27]AmCham EU (2012), Investment in Healthcare;accessed: 17/09/2014); p. 2
[28]Ibid

[29] AmCham EU (2013), Forever Healthy. The Healthcare Consumer 2020, p. 42;(accessed: 17/09/2014)
[30] European Commission (2010), Europe 2020. A strategy for smart, sustainable and inclusive growth; COM(2010) 2020; p. 3
[31] Brand H, Palm W (2014), Health and European integration: part of the problem or part of the solution? Eurohealth 20,3: 5-7
[32] OECD (2008), Pharmaceutical PricingPolicies in a Global Market.OECD Health Policy Studies; p. 24
[33] See:http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform_access/index_en.htm (accessed: 17/09/2014)