



# Recommendations to the Finnish Presidency of the Council of the European Union

July - December 2019



# AmCham EU speaks for

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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 more than **€2 trillion in 2018**, directly supports more than **4.8 million jobs** in Europe, and **generates billions of euros** annually in income, trade and research and development.

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# Message to the Finnish Presidency of the Council of the European Union



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The Finnish Presidency of the Council of the European Union (EU) comes at a key moment for the future of Europe. This coincides with the beginning of a new legislative term, the continued negotiations on the future EU-UK relationship and ongoing trade tensions between the EU and US. At such a crucial time, the Finnish Presidency will assume an important role in framing the next European agenda and steering the EU in the right direction for 2019 and beyond.

In an uncertain international environment, the case for strong transatlantic cooperation has maybe never been as compelling. The EU and the US are the drivers of global growth. Our economic partnership is vibrant: it represents the largest and wealthiest market in the world. Aggregate US investment in Europe totalled more than €2 trillion in 2018 and directly supports more than 4.8 million jobs in Europe.

We look forward to working closely with Finland during their Presidency to ensure we reach our common objectives of a stronger and more competitive Europe which creates jobs, meets consumers' needs and generates wealth for its citizens. This is why I am delighted to present these recommendations to the Finnish government on behalf of the American Chamber of Commerce to the EU (AmCham EU) and our member companies. We hope they will provide concrete input and direction to the Presidency's work programme. We believe that many of the issues raised by AmCham EU in this report are vital to creating sustainable economic growth.

AmCham EU stands ready to support Finland in this crucial role, and wish the Presidency every success.



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## American companies invested in Europe

American companies have deep and longstanding ties in Europe. Along with creating jobs, developing infrastructure and driving innovation, American companies also invest in people and communities through social and educational programs, research and development or environmental and health initiatives.

Find out more about these investments and their social impact on the 'Invested in Europe: Our Stories' platform. It brings together initiatives led by U.S. companies tackling student poverty in France, building youth facilities in Bulgaria, creating low-emission mobility options in Belgium or developing new infrastructure for the Internet of Things in Germany.

# Committed to Europe: Agenda for Action 2019-2024

The last five years have tested European unity and the post-war world order. From the Brexit vote to the rise of populism, the EU had to demonstrate its ability to take the lead and deliver for European citizens. As the effects of digitalisation and globalisation continue to transform our economies, societies around the world are pressured to become more resilient.

As American companies committed to Europe, the competitiveness of the region in the global economy is of the utmost importance to us. We play a key role in supporting and ensuring we contribute to making a stronger EU that continues to be a powerful innovation hub and preferred investment destination.

As the 2019-2024 legislative term begins, AmCham EU has set forth its vision and taken the unique opportunity to engage in the debate on the future of Europe and the EU's priorities for the next five years. Building on previous initiatives led in 2009, 2014 and before, this Agenda for Action outlines the four priority areas we believe should drive the political agenda:



## Empowering people

- Education
- Skills
- Inclusion



## Leading global cooperation

- Transatlantic partnership
- Trade and investment
- Sustainability



## Boosting the Single Market

- Smart regulation
- Better harmonisation and implementation
- Capital, digital, energy and transport



## Investing in the future

- Human capital
- Research and innovation
- Infrastructure and best-in-class public procurement

Learn more: [www.amchameu.eu/Agenda4Action](http://www.amchameu.eu/Agenda4Action)

# Policy recommendations by Council configuration

## Agriculture and Fisheries

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### ISSUE

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### RECOMMENDATIONS

#### **Implementation of the legal framework for veterinary medicinal products**

The Regulation on veterinary medicinal products (VMP) seeks to put in place an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector. The core objective is to increase the availability of VMP and improve the functioning of the internal market, reduce administrative burden and stimulate innovation. An additional objective is to strengthen the EU's action to fight Antimicrobial Resistance (AMR).

The implementation of this Regulation should reflect a sound benefit-risk assessment, not hazard-based approaches. It should not hamper international trade by imposing EU technical/practical measures on third-countries that are not compatible with World Trade Organization (WTO) rules. This relates to the setting up of a list of critically important antimicrobials (CIAs) and prohibiting the import of animals and animal products treated with these CIAs in third countries.

#### **Risk assessment, management and communication in the agro-food sector**

A balance between risk assessment, management and communication is of paramount importance for the integrity of the food chain and to allow and promote an innovative and sustainable food sector. Risk management decisions should be communicated in a clear and transparent way to foster and encourage (rather than discourage) consumer acceptance of technological developments. Rigorous scientific and risk-based decision-making should be at the centre of all discussions.

#### **Reform of the Common Agricultural Policy**

The EU should prioritise five principles to meet growing global demand for food while adopting more sustainable farming practices and insuring the future of our farmers.

1. Empower farmers through market driven policies, allowing them to respond to price signals while providing a safety net where necessary;
2. Retain the commonality of the Common Agricultural Policy (CAP) to protect the Single Market – in view of the new architecture of National Strategic Plans;
3. Enable farmers to achieve more sustainable and efficient farming practices. Livestock production necessitates a shift in the approach of animal health management by implementing more preventive measures, including vaccination. Farmers should not only be helped, but also incentivised to adopt more sustainable practices. In the era of digital health, new technologies allow for a better and more accurate monitoring of an animal's condition and support the prevention of diseases outbreak (eg, electronic ear tags, collars). Beyond improving animal welfare, new technologies also increase the well-being of our farmers;

## Agriculture and Fisheries (cont.)

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### ISSUE

**Reform of the Common Agricultural Policy**  
(cont.)

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### RECOMMENDATIONS

4. Support R&D initiatives in agriculture including digital and precision farming. Member States should facilitate access to these new technologies and should leave no rural area behind; and
5. Promote a global playing field and non-discriminatory treatment of local versus imported raw materials needed to supply the European market.

## Competitiveness

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### ISSUE

**Single Market**

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### RECOMMENDATIONS

The Single Market is the basis of the economic success of Europe and a key determinant of US investment in Europe. Completing the Single Market could help boost EU gross domestic product (GDP) by around four percent over the next ten years. It would increase productivity, investment, trade and job creation, helping to ensure Europe maintains its position as a global economic leader.

Pressure on the Single Market has increased, particularly given the United Kingdom's (UK) decision to leave the EU, in addition to policy challenges of migration and an increasingly nationalised and fragmented EU decision-making process. However, there is now a key opportunity with the Finnish Presidency setting the agenda for the next mandate to strengthen Europe's competitiveness on the world stage by further harmonising the rules and acting as a united block.

The will of EU policy-makers to complete the Single Market is clear - as demonstrated by the Commission's Single Market Strategy. However, greater action at Member State level is still needed to ensure the integrity of the market in the long-term and to promote investment and innovation in Europe. Strong Member State coordination and leadership, in partnership with EU institutions, key stakeholders and the business community, is necessary for Europe to be able to face new challenges and be a successful and effective marketplace.

**Industrial competitiveness**

Europe faces increased global competition for investment. To tackle the downward trend of investment in manufacturing, Member States should focus on implementing structural reforms and fully leverage the European Semester reports and recommendations. We need the right conditions to conduct business and ensure a solid infrastructure, to foster skills, talent, innovation and labour flexibility. At the EU level, these measures should aim to strengthen the Single Market, encourage free and rules-based trade and the effective implementation of the Better Regulation agenda.

# Competitiveness (cont.)

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## ISSUE

### Centralised customs clearance and one-stop shop

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## RECOMMENDATIONS

All customs formalities should be handled through a single customs office in any Member State, rather than the current requirement to separately clear goods in all 28 EU countries.

Regulatory controls (eg, veterinary, phytosanitary and agricultural) should be managed through a single information technology (IT) interface used and recognised by all Member States. This will eliminate red tape, saving time and money, as goods will only be stopped once for checks.

### Customs infringements and sanctions

Penalties for infringements should only be applied in cases of proven gross negligence or intentional fraud. These penalties should be levied on the basis of unpaid or underpaid duties, not on the value of the goods.

Both customs officials and companies need easily applicable and understandable rules which support and expedite trade rather than hamper it. They should serve as a tool, not an obstacle, particularly for small and medium-sized enterprises (SMEs), which are the growth engines of the European economy.

### Review of the pharmaceutical intellectual property incentives framework

The European Commission's review of pharmaceutical intellectual property (IP) incentives takes place in the context of controversy and debate on the sustainability of healthcare systems and drug prices. We acknowledge the importance of these discussions, but we do not believe that a review of the EU IP incentives framework will effectively address the sustainability of healthcare systems across the EU and respond to patients' needs.

The European incentives framework for the biopharmaceutical sector is made up of several components: patents, supplementary protection certificates (SPCs), regulatory data protection, paediatric rewards and orphan medicinal products (OMPs) specific measures. These are instrumental in driving investments and delivering innovative medicines to the benefit of patients and society as a whole.

These different incentives are time limited and are playing different yet complementary roles. For example, whilst patents, SPCs and regulatory data protection support innovation in general. Paediatric rewards and market exclusivity associated with OMPs encourage research and investment in a specific patient population, where there is a market failure and an unmet medical need persists.

The current intellectual property rights (IPR) framework in Europe has demonstrated over the past decades that it is working. Overall, the system provides incentives and rewards where required. It balances the need to reward innovation with the needs of competition, it allows for innovation while not extending exclusivity in perpetuity and it protects innovator's investments while allowing generic providers to prepare for market entry. Furthermore, it:

- Continuously delivers today's medicines and unlocks tomorrow's cures, sustaining an innovation cycle that supports the knowledge-based economy;
- Allows science to progress for the benefit of patients, especially in areas of high medical need. Innovations are not kept confidential in the form of trade secrets, but instead disseminated, early on, to the entire community; and



# Competitiveness (cont.)

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## ISSUE

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## RECOMMENDATIONS

**Review of the pharmaceutical intellectual property incentives framework**  
*(cont.)*

- Enables society, upon loss of exclusivity, to benefit from the same value at a lower cost – as today’s innovative medicines become tomorrow’s generics.

The Finnish Presidency should consider that weakening the above IPR framework would reduce the development of and access to innovation healthcare. This could negatively impact healthcare outcomes, scientific research and the EU’s economy. Instead, the EU should look at other areas where urgent action is needed. A clear example is the fight against AMR. To stimulate early- and late-stage R&D in novel antimicrobials, vaccines, rapid diagnostic tools and alternatives, a package of ‘push’ and ‘pull’ incentives should be designed and implemented in collaboration with industry.

**Enforcement intellectual property rights**

Strengthening the existing IPR protection framework is an efficient way to secure innovation and investments in the EU. The protection of IPR will facilitate the creation of a sustainable Single Market in which brands and consumers can – both on- and offline – interact confidently and safely.

The Commission’s approach for increased cooperation among stakeholders (eg, through codes of conduct) and its commitment to a better enforcement of IPR within the Single Market, is a step in the right direction. The guidance on the implementation of the IPR Enforcement Directive (IPRED), published in November 2017, should assist in creating more legal certainty for all participants in the IP system and increasing consumer protection.

However, more will need to be done if we want to meaningfully address the issue of piracy and counterfeiting, which continue to grow, both in size and scope. Figures published in March 2019 jointly by the European Union Intellectual Property Office (EUIPO) and the Organisation for Economic Co-operation and Development (OECD) show that counterfeiting and piracy now represent 6.8% of all products imported into the EU, as opposed to 5% just three years ago.

**Tackling illegal content online (with regard to IPR infringements)**

AmCham EU supports the Commission’s objectives to address legitimate concerns around illegal content online and shares the view that this content has the potential to seriously compromise economic growth and jobs, as well as damage consumer protection and safety overall.

**Unitary patent**

A fully functioning unitary patent (UP) system would signal that IP is a driver of innovation, competitiveness and growth for Europe in a global economy. We encourage Member States to ratify the agreement of the UP Court (UPC) to move forward with the implementation of the UPC and UP system.

**Hague Convention on the recognition and enforcement of foreign judgments**

The Convention is an important tool to foster judicial cooperation and the rule of law in appropriate legal areas, but the inclusion of IPR in its scope – as the European Commission supports – would have unintended consequences. Recognising judgements from vastly different national systems of IP protection and enforcement will be to the detriment of industry in Europe.

## Competitiveness (cont.)

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### ISSUE

**Hague Convention on the recognition and enforcement of foreign judgments**  
(cont.)

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### RECOMMENDATIONS

In addition, given significant differences in sanctions and remedies between national systems outside the EU, such a system would encourage forum shopping and create legal uncertainty for rightsholders in Europe. Finally, no impact assessment and broader stakeholder consultation have been conducted to substantiate the position of the EU, despite the potential negative impacts identified by the business community.

## Economic and Financial Affairs

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### ISSUE

**Market openness**

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### RECOMMENDATIONS

Open, well-functioning and appropriately regulated transatlantic capital markets are a crucial driver of long-term economic growth and are inextricably linked to competitiveness in Europe.

As EU policy-makers further consider the future supervisory and regulatory framework for third-country market access, we would ask for the following recommendations to be kept in mind:

- Increased transparency and predictability around the equivalence process. This should include greater certainty over the determination and withdrawal of equivalence; and
- Mutual deference to one another's regulatory and supervisory regime, wherever possible, should become the preferred approach, supplemented by adequate cooperation and exchange of information agreements that can further foster trust.

**Capital Markets Union**

AmCham EU supports efforts to complete the Single Market for financial services, including the Capital Markets Union (CMU) agenda. We strongly believe that the CMU needs to remain a priority for the next Commission, with renewed focus on the creation of open, innovative and sustainable financial markets. In addition, Brexit may create additional market fragmentation, which will increase obstacles to cross-border investments and efficient capital allocation.

In continuing to build the CMU, we highlight four areas which we see as important:

1. Already legislated initiatives (eg, securitisation, prospectus, venture capital) should be assessed for purpose in terms of delivering on the objectives of developing market-based funding channels and unlocking access to finance for SMEs and infrastructure projects;
2. Ongoing and future initiatives should strive to avoid fragmentation of global liquidity pools. The approach to market access should not be driven by localisation agendas (eg, based on currency or assets under management, or via restrictions on delegation and outsourcing), nor should they systematically impose stringent wide-reaching conditionalities

# Economic and Financial Affairs (cont.)

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## ISSUE

### Capital Markets Union

(cont.)

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## RECOMMENDATIONS

(eg, based on perceived risks to financial stability or of inadequate financial crime frameworks);

3. Concrete follow-ups should emerge from the Commission's FinTech Action Plan and Europe's approach to technology neutrality (eg, vis à vis the scaling up of FinTech's and clarification on the treatment of digital assets). A balance needs to be maintained between encouraging innovation (eg, in payments) and creating level playing field conditions for fair competition; and
4. Better leverage private capital to meet EU climate and sustainability goals in the Commission's Sustainable Finance Action Plan. In line with the principles of the CMU, we recommend that initiatives take an open, flexible and outward-looking approach to ensure equal and non-discriminatory access for third-country financial institutions.

### Banking Union

AmCham EU is a long-standing supporter of European rules aimed at strengthening financial stability via improvements to prudential requirements, as well as to recovery and resolution mechanisms.

Looking ahead to the next Commission's agenda, we believe that the overarching priorities of the EU in the field of prudential regulation should be to complete the Banking Union, to ensure a globally consistent implementation of international banking standards (Basel framework) and to avoid fragmentation and localised ring-fencing requirements.

- An EU liquidity backstop mechanism is still urgently needed to prevent contagion of future resolution situations inside the Banking Union and the development of potential future systemic crises. The Single Supervisory Mechanism (SSM) and Single Resolution Mechanism (SRM) have already helped in managing the first bank liquidations/resolutions in Italy and Portugal;
- Divergences and inconsistencies in the implementation of the Basel standards should be avoided, as they can distort competition and lead to the misallocation of capital in the financial system, to the detriment of overall growth. AmCham EU encourages EU policy-makers to implement the rest of the Basel package, including the outstanding Fundamental Review of the Trading Book (FRTB) capital standards, without significant divergence from the hard-won global agreement and in order to strengthen the existing Banking Union framework; and
- European policy-makers should further promote free flows of capital and liquidity by avoiding regulation that increases fragmentation and ring-fencing of capital and liquidity, or prevents cross-border groups from managing them centrally. At the heart of banks' ability to service their global customer base and support the European economy is their ability to allocate capital and liquidity where it is most needed.

# Economic and Financial Affairs (cont.)

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## ISSUE

### International tax

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## RECOMMENDATIONS

The OECD is the best forum for a coordinated and coherent approach to the taxation of multinational companies and the consistent adoption of the OECD's Base Erosion and Profit Shifting (BEPS) recommendations across the EU. Going beyond the recommendations would negatively impact the EU's attractiveness for investment from EU and third-country companies. A unilateral EU approach to the direct taxation of multinational companies could create double taxation problems and reaffirm concerns about protectionism. This is especially true if it is not coordinated with the ongoing multilateral tax discussion at the OECD level.

For example, the taxation of the digital economy needs to strike the right balance between taxing value where it creates and fosters growth. A serious, structured conversation about how new business models should be taxed should take place in a multilateral context in order to ensure widespread agreement. The EU can bring valuable expertise, but there are concerns that unilateral measures (eg, France, Austria or Italy) may make it more difficult for that process to succeed.

### Sustainable finance

AmCham EU believes that it will be critical to leverage the experience of the private sector to support the transition to a sustainable economy. It is only with the help of the financial sector that we can meet the €180 billion annual funding gap to reach EU climate and energy targets.

To ensure the lasting success of the sustainable finance project, we believe the following principles will be crucial:

- Regulatory certainty and economic stability: it is essential that the EU ensures a coherent, holistic and long-term framework to promote sustainable growth. This includes clear and objective definitions of 'green', without which investors would lack regulatory certainty. In the interests of financial and economic stability, complex default or market risk must be taken into account as a pre-requisite for sound action;
- Evidence-based policy: business is uniquely placed to provide expertise on the real-world challenges associated with climate change and the impact of transition orientated policy initiatives. Policy-makers should ensure that evidence drives decision-making and that all stakeholders are able to provide meaningful and substantive input; and
- International openness: the EU's leadership is critical to building international momentum on sustainable finance. However, the ambitious energy transition targeted in the Paris Agreement requires the mobilisation of global financial markets. In line with the principles of the CMU, we recommend that EU initiatives take an open and outward-looking approach to ensure equal and non-discriminatory access for third-country financial institutions, businesses and investors.

# Employment, Social Policy, Health and Consumer Affairs

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## ISSUE

### REFIT of consumer law

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## RECOMMENDATIONS

The Commission's efforts to improve enforcement of consumer protection rules are essential to safeguard consumers and ensure fair competition between traders in the Single Market. However, the revised text adopted fails to remedy the core of the issue, which is a lack of awareness of consumer rights and insufficient coordination between Member States. AmCham EU recommends to:

- Increase the level of awareness of consumer rights for traders, consumers and consumer associations to avoid insufficient compliance and high fines that can jeopardise business operations in a disproportionate manner if the non-compliance is due to lack of knowledge.

### Health Technology Assessment

AmCham EU supports the Commission's proposal on health technology assessment (HTA) and its aim to harmonise the assessment of clinical evidence and avoid duplication of processes across Member States. Despite the ongoing challenges in Council, we encourage the Finnish Presidency to adopt a balanced approach and methodology that improves patient access, while adequately reflecting the specificities and the differences between each sector of the healthcare industry. AmCham EU's recommendations are:

- Reach alignment on clinical evidence requirements and generation in order to reduce duplication, pool expertise and speed up access to new pharmaceutical treatments. Also, preserve Member State autonomy to perform country-specific socio-economic appraisals and make decisions regarding pricing and reimbursement (P&R);
- Limit the scope of the Regulation to joint clinical assessment and scientific consultation for pharmaceutical products;
- Support the mandatory uptake of joint clinical assessments for pharmaceutical products; and
- Ensure cross-stakeholder consultation, including in the formal stakeholder network.

### Improving access to health

AmCham EU supports the Finnish Presidency's focus on improving access to healthcare in Europe. In order to build safe, accessible and effective health systems that reduce healthcare inequalities and boost the economy, AmCham EU recommends to:

- Take a holistic approach to healthcare policy that accounts for the mix of services and products needed for treatment as part of an integrated life sciences strategy. Create the potential of budget headroom for innovation and to improve access by looking at the life cycle of health spending over a longer-term period;
- Improve patient outcomes and help relieve pressure from the healthcare systems' budgets. Finland has been making efforts to integrate healthcare delivery and to incentivise outpatient care, in cases where it is possible and justified, by removing budget silos and supporting a shift of care from the hospital towards the community or the home. Such initiatives should be promoted and the EU should play an active role in fostering these discussions and promoting best practice exchanges;

# Employment, Social Policy, Health and Consumer Affairs (cont.)

## ISSUE

### Improving access to health

*(cont.)*

## RECOMMENDATIONS

- Safeguard innovation by implementing dynamic efficient policies that balance concerns in the short-term (eg, cost-containment) with the longer-term (eg, R&D investment and innovation in health care). Policies such as external reference pricing (ERP) can undermine patient access to medicines;
- Avoid arbitrary cost-containment measures that potentially limit patient choice and curtail safety standards and regulations (eg, through full-class tendering), or the promotion of economically-driven off-label use of medicines which can compromise patient safety;
- Promote the use of managed entry agreements and pay for performance contracts to help balance innovation, patient access and sustainability. Such as advanced therapy medicinal products (ATMPs), and encourage Member States to address the specificities of new innovative therapies in their national uptake and early engagement between payers and companies;
- Strengthen IP incentive frameworks to boost biopharmaceutical R&D;
- Support innovative partnerships between public and private sectors; and
- Foster health literacy to empower citizens and patients as they contribute to better health outcomes and more efficient resource use (ie, innovators in their own health – digital health solutions).

### Fighting Antimicrobial Resistance

AmCham EU welcomes the Finnish Presidency's aim to focus on the growing cross-border public health threat posed by AMR. The EU can and should serve as a leader in the fight against AMR. The implementation of the One Health Action Plan (linking animal and human health as well as environmental health) should be high on the list of priorities. Member States should work together with the European Commission towards the following key objectives:

- Promote antibiotic stewardship to preserve the effectiveness of existing treatments;
- Expand and better coordinate surveillance tools and increase our knowledge of the mechanisms of resistance;
- Advocate for a broader and more effective use of vaccines and new technologies such as medical devices and diagnostics; and
- Develop and implement new economic models and incentives to stimulate R&D in new antibiotics, vaccines and rapid diagnostics.

### Digitisation of health

The Finnish Presidency's focus on the digitisation of healthcare rightly recognises the need to harness digital technologies to improve access and quality of treatment. Both electronic health (eHealth) and mobile health (mHealth) are key enablers of sustainable healthcare systems in Europe. They are based on the exchange of electronic health information, are highly personalised and focused on patient empowerment.

# Employment, Social Policy, Health and Consumer Affairs (cont.)

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## ISSUE

### Digitisation of health

*(cont.)*

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## RECOMMENDATIONS

The steps undertaken as a result of the European Commission's April 2018 communication on the transformation of health and care in the Digital Single Market (DSM), should lead to policies that engage citizens, healthcare providers and companies. This will enhance care outcomes, promote self-management, improve safety and lower health costs. In light of the transatlantic eHealth/health IT cooperation roadmap, efforts should be directed towards system interoperability, expanding the adoption/exchange of eHealth records and allowing citizens to access their medical information and related services online, including on mobile devices. This must be done with the appropriate safeguards in place to ensure the secure transfer of data and in compliance with the General Data Protection Regulation (GDPR).

### Life sciences

The healthcare industry looks very different to how it did ten years ago. Innovation in health technologies – pharmaceuticals, medical devices, diagnostic technologies and increasingly, digital health – have revolutionised healthcare and transformed the way we deliver and manage treatments and organise healthcare systems.

There is an increasing use of integrated treatment options (that combine pharmaceuticals, medical devices, diagnostic technologies, and digital health solutions), offering significant benefits to patients, the healthcare system and society. However, while their integration is offering unique opportunities to boost innovation and improve health outcomes throughout Europe, it is also posing novel challenges across the life sciences sector. Therefore, policy-makers should give sufficient attention to this sector and create an integrated life sciences strategy for the EU.

As we move into the start of a new legislative term, we have set out policy solutions to promote more favourable conditions for incentivising innovation that benefits patients, to encourage its uptake and address the common healthcare challenges and issues. Learn more by reading 'Life Sciences for Europe: an integrated strategy for healthcare innovation (2019-2024)', found at, [www.amchameu.eu/lifesciences4eu](http://www.amchameu.eu/lifesciences4eu).

### Future of work, education & skills

The digital revolution will lead to a fundamental change in Europe's skills demands. The mismatch between business expectations and the skillsets of young graduates continues to grow, while the active workforce needs upskilling and reskilling to remain competitive.

These issues can only be partially addressed at Member State level. We need a Europe-wide review of how human capital is built and develops throughout an employee's career. As such, EU institutions should facilitate the sharing of best practices and encourage concrete initiatives and partnerships between public and private actors. EU funds should be used to set up apprenticeship opportunities and to strengthen vocational training and adult learning opportunities for the active workforce. Legislative work, however, remains essential, for instance in the case of the recognition of professional qualifications and the alignment of micro-credentials across the Single Market.

# Employment, Social Policy, Health and Consumer Affairs (cont.)

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## ISSUE

### Gender balance

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## RECOMMENDATIONS

Although Europe has come a long way, women continue to be heavily underrepresented in strategic sectors as well as in leadership positions. This remains striking as research overwhelmingly points to the economic benefits of promoting women leadership in the workplace.

AmCham EU praises the Finnish Presidency's commitment to tackling gender issues and look forward to taking part in their efforts. In a forward-looking perspective, the Finnish Presidency should seek to ensure a continued focus on these topics throughout the next five years, but also broaden the scope of action to diversity and inclusiveness. Rather than through a sectoral approach, female empowerment should be addressed in a horizontal, cross-sectoral fashion, as it spills over into a variety of policy areas, including healthcare, trade and employment.

# Environment

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## ISSUE

### EU strategy for long-term greenhouse gas emissions reduction

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## RECOMMENDATIONS

The EU has taken a leadership role in climate policy, setting itself ambitious targets and should use its position to leverage action with its main global partners to meet the Paris climate ambitions. Developing the 2050 strategy is clearly a challenging task which should start by ensuring that fundamental principles like sustainability, technology neutrality, predictability and transparency are encompassed in the existing and future regulatory framework.

Working on the following aspects would stimulate private efforts to reach the overarching objective:

- Ensure environmental protection: achieved through responding to consumer preferences and continued investment in innovative technologies that create a sustainable environment for growth in a low-carbon society. The EU and Member States should target policies to communicate consistent and harmonised information towards consumers and facilitate a stable regulatory framework that drives investment during the transition;
- Foster a competitive economy: investment in innovative technological solutions can encourage competition between companies. Policy-makers should allow equal access to public funding and endorse technology neutrality. For example, innovation throughout the transition should significantly support technologies that aid in a gradual reduction of harmful emissions; and
- Empower people: the low-carbon economy will hinge on well-equipped and highly-skilled labour forces that are adapted to the needs of tomorrow. Educators and governments should work with business to increase the stock of future relevant skills to support the industrial transition.



# Environment (cont.)

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## ISSUE

### Emissions Trading Scheme reform proposal

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## RECOMMENDATIONS

As more focus turns to the implementation of the emissions trading scheme (ETS), there is still room for improvement to support competitiveness and investment in Europe. Policy-makers should ensure a stable regulatory framework and prevent national interventions which distort market mechanisms.

AmCham EU recommends:

- Enhanced compensation of indirect costs for the industry; and
- Consistency between funds and clarity on the eligibility of industry projects for funding.

### Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation

Over the past few years, the implementation of Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) has improved. Nevertheless, more could be done to guarantee REACH delivers on safety without jeopardising competitiveness and innovation in Europe.

Several aspects could be improved to ensure a highly efficient system that is inclusive of all stakeholders and does not overburden industry:

- Clarify timelines for different REACH processes;
- Avoid unequal treatment by Member State competent authorities when it comes to substance evaluations;
- No 'data for data's sake'. Data requirements should be proportionate and not go beyond what is needed;
- Prevent overlaps between the various REACH processes and sectoral policies;
- Streamline the authorisation process and formalise the risk management option analysis (RMOA); and
- Recognise the impact of REACH on predictability and long-term investment in Europe, specifically when it comes to innovation and the global competitiveness of Europe versus the rest of the world.

### Restriction of Hazardous Substances

Restriction of Hazardous Substances (RoHS) has been a highly effective market access law that has been copied in over 40 jurisdictions globally and is valued by industry for the clear signals it sends. As the Directive comes up for review, the following should be considered to build upon previous strengths:

- Improve the exemption process through clearer timelines and exemption periods in line with business practices;
- Changes to RoHS need to respect its international success, as these could delineate the EU framework from others and result in additional burdens for industry;
- Recognise RoHS's linear nature when integrating circular economy considerations; and
- Support the use of existing ecotoxicological data in RoHS jurisdictions outside of the EU.

## Environment (cont.)

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### ISSUE

#### Resource efficiency and the EU circular economy action plan

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### RECOMMENDATIONS

Significant progress has been made in supporting the development of a circular economy in the EU. In order to build upon initial successes and establish a circular economy that benefits all, the following should be considered:

- Ensure a consistent implementation across Member States and on developing the necessary infrastructure;
- Provide sufficient economies of scale for the development of new business models through an effective Single Market for secondary raw materials;
- Create global loops rather than closed borders;
- Clarify circular economy objectives and how these interact with existing regulatory frameworks;
- Ensure a proportionate sharing of costs and responsibility along the value and waste management chains; and
- No one-size-fits-all solution, a sectoral approach is needed to promote the circular economy.

## Foreign Affairs and General Affairs

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### ISSUE

#### Brexit and EU-UK trade and investment relationship

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### RECOMMENDATIONS

The UK's impending withdrawal from the EU is raising important questions for US companies, who are heavily invested in both the EU and UK. After two years of negotiations, the failure to reach an agreement on a transition period has resulted in great costs for business, which needs certainty about the path forward for the new EU-UK relationship.

It is therefore essential that the EU and UK agree on and ratify a Withdrawal Agreement without further delay. An orderly UK exit will avoid the possibility of a damaging cliff edge scenario, which would bring enormous disruption and economic costs for business and citizens alike.

In the future, the two parties should be looking to agree on a new relationship that builds on the deep and comprehensive links that underpin EU-UK ties, limits disruption and uncertainty, resembles the effects of the Customs Union and preserves the integrity of the Single Market. In addition, ensuring citizen rights and cross-border data flows are also key elements of the future relationship. Scoping for the future relationship should begin as soon as a Withdrawal Agreement has been finalised.

# Foreign Affairs and General Affairs (cont.)

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## ISSUE

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## RECOMMENDATIONS

### Brexit No Deal contingency planning

The Finnish Presidency should endeavour to further coordinate Member States' work on No Deal preparations together with the European Commission. In areas such as financial services, contingency planning has been delegated to Member States, resulting in a patchwork of 28 different regulatory regimes. In other cases, contingency planning is not foreseen, with considerable risk for the supply of critical products such as medical devices and pharmaceutical products.

It is essential for companies to rely on a set of certain contingency measures in a No Deal scenario. This will help mitigate the enormous disruptions of a No Deal Brexit, allowing companies to continue operating a minimum level of cross-border trade.

### EU bilateral trade relations

The Finnish Presidency should support the early conclusion of free trade agreements (FTAs) that are:

- WTO compatible;
- Ambitious in coverage;
- Balanced;
- Capable of strengthening and complementing the multilateral trading system;
- Contributing to the development of trade and investment friendly standards, rules and principles;
- Enabling cross-border data flows and prohibit data localisation; and
- Promoting better protection of IPR.

Constructive dialogue with major trading partners, including the US, is key to enhancing mutual understanding, economic growth and prosperity. US business in particular urges a de-escalation in the current transatlantic trade disputes which could threaten jobs and growth on both sides of the Atlantic.

### Role of the World Trade Organization

The current gridlock at the WTO is a cause for significant concern. A strong WTO acts as an important guarantor of legal rights in international trade and investment for business and society. Further market liberalisation and development of multilateral rules would boost global economic recovery for developing and developed countries alike.

The EU and its global partners should work to strengthen the principles of the multilateral trading system, through active participation at the WTO level. The EU should conclude multilateral and plurilateral agreements with global partners and promote the rule of law through a reinforced and fully functioning dispute settlement mechanism.

### Export control of dual-use goods

As cyber threats evolve, heavy-handed regulation stifles innovative responses. Labelling cyber surveillance technology as dual-use could undermine the ability of legitimate EU and foreign users to protect themselves, without effectively deterring malicious parties from accessing truly harmful technological capabilities.

# Foreign Affairs and General Affairs (cont.)

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## ISSUE

### Export control of dual-use goods (cont.)

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## RECOMMENDATIONS

Some of the proposed requirements could put a disproportionate burden on companies. A better balance of responsibilities should be struck between industry and national authorities, who are better equipped to gather intelligence on matters such as risks of human rights violations and terrorism.

Export controls should be regulated at the international level through multilateral regimes, such as the Wassenaar Arrangement, that are able to bring together countries from across the globe. Undermining such initiatives could risk the international competitiveness of the EU.

### Common Security and Defence Policy and the European Defence Action Plan

Systematic domestic preference for defence capability developments in Europe, justified by the notions of 'buy European' and 'strategic autonomy', will not only harm economic growth and transatlantic defence cooperation, but ultimately weaken collective security. The Commission's report on the implementation of two directives, Defence Procurement and Intra-Community Transfers and its recent European Defence Action Plan (EDAP), are opportunities to remedy this by:

- Creating an open EU procurement and funding process. Encouraging US defence industry participation to reinforce enhanced transatlantic defence industrial cooperation (TADIC);
- Recognising the footprint and contributions to the European Defence Technological and Industrial Base (EDTIB);
- Encouraging transatlantic cooperation through EU-US programmes that enhance interoperability and operational efficiency; and
- Streamlining bureaucratic processes to create a competitive transatlantic marketplace.

### European Space Programme

A European Space Programme (EUSP) will provide vital funding and establish a critical framework for the development of a robust European space sector. International partnerships are essential for the development and competitiveness of the industry, the following will be essential in ensuring its continued success:

- Openness of space markets as an essential prerequisite for sustainable and mutually reinforcing transatlantic space cooperation;
- Reciprocity and a level playing field; and
- Clear and proportionate participation criteria for third-country entities to provide business and investment certainty.

### Enforcement of IPR in third countries

The Commission's initiative to set up a Counterfeiting and Piracy Watch List for marketplaces outside the EU is a step in the right direction. AmCham EU supports the strengthening of international efforts against counterfeiting and piracy and to encourage sustainable and meaningful actions to prevent IP violations throughout the global supply chain. Enforcement of IPR by the EU in third countries (eg, China, Russia, Ukraine, etc.) and greater cooperation between the EU and US in the definition and implementation of IPR enforcement strategies needs to continue.

The Council should promote the activity of the European Observatory on Counterfeiting and Piracy to fight counterfeiting and piracy.

# Justice and Home Affairs

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## ISSUE

### **General Data Protection Regulation**

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## RECOMMENDATIONS

It remains crucial that the GDPR is applied in a uniform and balanced way at national level. Discussions will continue on the interpretation of the GDPR and its application in the context of emerging technologies, such as Blockchain and artificial intelligence (AI). It is essential that the data protection authorities and the European Data Protection Board (EDPB) consult regularly stakeholders, ensure a strong dialogue with industry and guarantee a harmonised interpretation of the GDPR rules across Europe.

### **Representative actions for the protection of collective interests of consumers**

AmCham EU supports the Commission's efforts to facilitate access to justice and guarantee a high level of consumer protection. In some cases, it may be appropriate to achieve this through collective redress mechanisms. However, the proposal to introduce 'representative actions' does not include the full range of safeguards outlined in the Commission's 2013 recommendation to Member States. Without the full implementation of these recommendations, there is a serious risk that the EU will inadvertently introduce a US-style class action system, in which access to justice becomes a business, benefitting law firms and third-party funders rather than consumers.

### **Cross-border access to electronic evidence**

The Commission's e-evidence proposals have the potential to significantly increase legal certainty and provide a basis for an international agreement. However, for the EU to set the right international precedent and create a workable framework, it should respect existing jurisdictional standards and provide strong procedural and material safeguards.

The extremely high fines proposed in the Council's general approach are disproportionate and, as the European Parliament's working documents point out, they may not even be legal under the Treaties. Long-term solutions can only be achieved with an EU-US agreement on law enforcement access. AmCham EU welcomes the Commission's proposed mandate and encourages the swift start and conclusion of the negotiations.

### **Preventing dissemination of terrorist content online**

AmCham EU is fully committed to combating online terrorism as the threat posed to democratic societies is immense. Our aim is to help design constructive and workable solutions, including through a targeted approach, to address this common threat.

AmCham EU believes that the position of the European Parliament (adopted on 17 April 2019) has improved the initial proposal. This has more precisely defined the scope of the legislation (targeted at storage of information 'made available to the public'; and explicitly excluding 'cloud providers, including business-to-business cloud services') and aligned the definition of 'terrorist content' with the 2017 Terrorism Directive (also mentioned in the Council's general approach).

## Justice and Home Affairs (cont.)

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### ISSUE

#### Preventing dissemination of terrorist content online (cont.)

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### RECOMMENDATIONS

We encourage co-legislators to maintain this approach in the upcoming trilogue negotiations and to address the following points to find workable solutions:

On removal orders (Article 4):

- Reconsider the one-hour delay, as it does not take into account technical problems and resources restraints of the variety of companies involved in the fight against terrorism online; and
- Clarify the role and nature of the competent authorities able to issue removal orders, as well as the consultation procedure between authorities (as proposed by the new Article 4a by the Parliament).

On proactive measures (Article 6),

- Provide more legal clarity on the obligation for proactive measures. We acknowledge the attempt to make the obligation more targeted ('depending on the risk and level of exposure to terrorist content'). However, this wording leaves room for interpretation and could be improved by stating that only hosting service providers 'which have systematically failed to address removal orders and refused to cooperate with competent authorities' should be obliged to adopt proactive measures. Similarly, the European Parliament text around competent authorities being able to send requests for additional proactive measures to providers that have received 'a substantial number of removal orders' is ambiguous.

## Transport, Telecommunications and Energy

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### ISSUE

#### Infrastructure investment

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The Commission's Investment Plan for Europe and the establishment and extension of the European Fund for Strategic Investments (EFSI) remains crucial. To keep Europe globally competitive, increased infrastructure funding is critical.

The proposal to create a new 'InvestEU' umbrella fund will simplify and optimise access to this funding. As discussions progress, policy-makers should ensure that European infrastructure funding remains focused on promoting technology neutrality, co-modality and avoiding market distortion. Furthermore, funding at the EU level should be supported and complemented by ambitious commitments from Member States.

#### Future Digital Single Market agenda

There is a strong case to unlock the potential of digital technologies in Europe and ensure their successful uptake across economic sectors. Businesses, governments and citizens can all benefit from the digital transformation. With this in mind, AmCham EU calls on the EU institutions to consider the following priorities for the next EU digital strategy:

# Transport, Telecommunications and Energy (cont.)

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## ISSUE

### Future Digital Single Market agenda (cont.)

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## RECOMMENDATIONS

- Rethink the way of doing policies and designing rules by adopting a more principle-based, risk-based and market-driven approach;
- Enact an ambitious agenda on emerging technologies, such as 5G, AI, blockchain and Internet of Things (IoT) by promoting targeted investments that foster their development and promote uptake across economic sectors and society;
- Create an enabling environment for investment, innovation and entrepreneurship to flourish by supporting R&D investments, international standards, skills, IP and competition;
- Build trust in the use of technologies by building strong public-private partnerships and applying existing regulatory frameworks; and
- Allow for businesses of all sizes to scale up and to trade at the global level by enabling data flows and tackling unjustified market access restrictions.

### e-Privacy

AmCham EU is strongly concerned by the impact on digital innovation across all economic sectors of the e-Privacy proposal in its current form. The latest presidency text (from 13 March 2019) has included some flexibility. However, further improvements need to be included:

- Align any future e-Privacy rules with the GDPR. The e-Privacy Regulation continues to focus on regulating processing rather than interference without foreseeing all necessary legal bases to allow the functioning of devices, services and features that rely on processing of communication data;
- Consider the unintended consequences of the proposal due to the broad scope of the regulation which includes machine-to-machine communication. In its current form, the regulation creates less compliance certainty and creates potential burdens for many emerging and fast innovating sectors who would fall under such rules;
- Introduce more flexibility on the permitted processing of communication content and metadata. Any 'all-party' consent requirement would outlaw email and any other interoperable communication services;
- Align different consent standards respectively for metadata, content data and for terminal equipment information. The language around consent requirements should be consistent and simply refer to 'end-user of the service has given his/her consent';
- Adopt a technology neutral approach: legislators should consider the impact of the suggested restrictions beyond cookies and browsers; and
- Take into account on-going discussions on 'e-evidence' and reference them both in Article 11 and Recital 26.

### AI and ethics

AmCham EU welcomes the comprehensive approach presented by the Commission on 25 April 2018 to unleash the development and uptake of AI across Europe. Governments, companies and civil society should work together to ensure AI brings benefits to all citizens across Europe.

# Transport, Telecommunications and Energy (cont.)

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## ISSUE

### AI and ethics

(cont.)

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## RECOMMENDATIONS

Industry has a role to play in supporting the responsible development of AI, such as encouraging the ethics guidelines for trustworthy AI published on 8 April 2019 by the independent High-level Expert Group (HLEG) on AI set up by the European Commission. The guidelines have been developed through a multi-stakeholder structure, they are actionable, proportionate and encourage an ethical approach to the technology. The EU should encourage a consistent approach to the development of ethical principles at an international level.

To foster the right policy environment, existing and new regulatory initiatives should be carefully assessed to avoid unintended consequences hindering AI uptake. AmCham EU is supportive of the efforts by the European Commission and other stakeholders to assess existing liability systems and would like to be fully involved in that process. Considering the fast evolution of technology and the inevitable obsolescence of rushed legislation, we are not convinced that there is an urgent need for new, specific liability rules for AI.

### Blockchain

Blockchain is an emerging technology which has the potential to transform the way we interact and exchange information in a faster, more secure and transparent way. At policy level, a good understanding of what blockchain is and does is essential for the development and broader adoption of distributed ledger technology (DLT), together with a clear and stable legal framework for its application in Europe. In particular, the key factors to boost blockchain in Europe could include:

- Legal certainty: is needed in areas such as the legal status of smart contracts, the GDPR compliance and classification of digital assets and tokens. This does not necessarily require new legislation, but rather guidelines and clarifications to ensure that the existing framework is fit for the blockchain era;
- Experimentation: the implementation of use cases and pilot projects in the public sector and the participation of governmental agencies in private projects would be the best way to test the technology in a large number of areas and promote its use; and
- No one-size-fits-all: the potential uses for DLT are numerous and diverse. Therefore, any regulatory framework needs to be sufficiently cognisant of the variety of potential applications of DLT which are adaptable to operating across multiple activities and services.

### 5G

For emerging technologies to succeed, the rollout of 5G will be essential. As rightly acknowledged by the European Commission, the fifth generation of telecommunication systems, or 5G, will be one of the most critical building blocks of our digital economy and society in the next decade. The connectivity benefits of 5G will give consumers access to information faster than ever before and will make businesses more efficient. Autonomous cars, smart communities, industrial IoT, immersive education and eHealth will all rely on 5G. The successful rollout of ultra-fast 5G services in Europe will require several factors, including but not limited to:

- Swift adoption and implementation of Member States' 5G roadmaps;



# Transport, Telecommunications and Energy (cont.)

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## ISSUE

### 5G (cont.)

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## RECOMMENDATIONS

- Quick and consistent implementation of the Electronic Communications Code by Member States; and
- Greater consistency of 5G spectrum and regular consultation and coordination among all relevant stakeholders.

### EU Cybersecurity Strategy

Public-private partnerships, harmonisation and global cooperation are the most effective ways to advance cybersecurity. With the exponential growth of connected devices, cybersecurity has become a major concern both for the online and physical world. When addressing security in the IoT space, it is essential to adopt a proportionate and risk-based approach, as well as to ensure consistency with international practices and standards.

The EU should focus on the harmonious implementation of the existing regulatory instruments to improve its cyber resilience. Through the adoption of the regulation on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation), the second Payment Services Directive (PSD2), the Network and Information Security (NIS) Directive and the GDPR, a comprehensive set of requirements has already been introduced for network and information system operators.

The recently adopted reinforced mandate for the European Union Agency for Network and Information Security (ENISA) (adopted with the EU Cybersecurity Act) is also an important step to prevent and react to cyber incidents. Harmonised security certification will reduce market fragmentation and provide a useful tool for industry. Therefore, it needs to be developed in close cooperation with relevant industry stakeholders and be based on international and European standards.

The challenge security brings is not just technical, but also deeply human. IoT security requires raising awareness amongst the entire community – vendors, service providers, industry, employees and consumers. Building and improving cybersecurity skills is critical and a responsibility of industry and governments.

The EU should continue to work with foreign partners, in particular the US, to adopt common approaches to detecting, mitigating and managing cyber risk at the international level. It is fundamental that the EU continues to strengthen its efforts to drive the international promotion of confidence building measures and norms of acceptable state behaviour in cyberspace.

### EU Cybersecurity Competence Centre and Network

The proposal for a Cybersecurity Competence Network coupled with a European Cybersecurity Research and Competence Centre is important in the EU's Cybersecurity Strategy. This initiative has the potential, if implemented appropriately, to reduce fragmentation, create synergies across the EU in research and investment as well as enhance industrial capacity building between Member States.

However, AmCham EU is concerned that the European Commission's proposal for a European Cybersecurity Network and a Competence Centre would exclude non-European headquartered companies from partnership and funding without duly justified reasons. Furthermore, the future Network and Competence Centre should build on a balanced governance system which gives an important role to ENISA, ensures consistency in national chapters and contributes to ongoing international work.

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*List accurate as of May 2019*

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