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DODS

THE PARLIAMENT

POLITICS, POLICY AND PEOPLE MAGAZINE

Issue 411
4 May 2015

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FRANS TIMMERMANS

... says he wants to ensure the EU institutions reach well informed decisions

The European Parliament Beer Club

Established in 1995, the European Parliament (EP) Beer Club is a cross party, transnational forum for discussion and information exchange amongst MEPs about issues that affect the brewing sector within the European Union.

JOIN THE EP BEER CLUB AND STAY INFORMED ABOUT BEER-RELATED ISSUES SUCH AS

- The contribution made by beer to Europe's socio-economic landscape and cultural patrimony;
- The work of Europe's 5000+ breweries to craft quality products for the enjoyment of Europe's responsible consumers; and
- How beer and the brewing sector can be affected (or enhanced) by policy developments across the EU.

A number of activities are arranged throughout the year, including briefings, events at the Parliament, beer tastings, brewery visits or report launches. A number of information tools are also shared with members such as newsletters and background briefings that allow MEPs to stay informed of developments within and affecting the beer sector.

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EP BEER CLUB OBJECTIVES

The **EP Beer Club** recognises the positive contribution made by beer to Europe's society, culture, economy and image.

The **EP Beer Club** believes that Europe should retain a strong brewing sector and supports a policy framework that nurtures this.

The **EP Beer Club** supports the positive role of beer in Europe's culture - reflected in the brewing traditions in all Member States.

The **EP Beer Club** seeks to foster a greater understanding of the brewing sector within the European Institutions, and particularly the European Parliament.

The **EP Beer Club** encourages the brewing sector to pursue its work as a responsible stakeholder.

A Responsible Approach to Animal Testing and Welfare Go Hand in Hand

Animal testing and the safeguarding of animals during the research process are emotive subjects. For MEP Françoise Grossetête, who lists health high on her policy agenda, the responsible use of animals in research is of paramount importance.

Grossetête's commitment to animal welfare is unwavering and continuous. Believing that it is of primary importance, and a key concern for European citizens, she signed the Animal Welfare pledge of the Eurogroup for Animals during the 2014 elections. "I am now being the rapporteur on the review of the veterinary medicines regulation, and one objective is to improve animal welfare through better availability of medicines to treat them," she says.

Grossetête notes that the European Union already is a leader at international level in this field and in the promotion of high standards of animal welfare protection. "Directive 2010/63 [on the protection of animals used for scientific purposes] has been a terrific step forward and provides Europe with one of the world's most restrictive regulatory framework for animal testing. I am proud to have taken part in working on this forward-looking piece of legislation," she says.

For Grossetête, the Directive has been a resounding success, simultaneously harmonising and raising the level of animal welfare standards across Europe while ensuring that the EU remains a leader in biomedical research. "One of the major achievements of this text is the introduction of mandatory ethical evaluation before research projects involving animals can be carried out. It is a key tool in ensuring that animal use in research is proportionate and responsible, when no alternative exist," she explains.

Furthermore, the requirement for researchers to consider the 3 Rs – replace, reduce, refine – when using animals in research are also important achievements of this piece of legislation. Grossetête believes that the 3Rs are indispensable to ensure animal welfare and that they set the necessary barriers to appropriately regulate animal testing – when and where it cannot be avoided.

"I think those principles actually form the backbone of our regulatory framework on the use of animals for scientific purposes. They guarantee that animals are only involved in tests when it is absolutely necessary and when there is no alternative, that those animals do not suffer or the least possible, and that only the necessary amount for the experiment is used," Grossetête stresses.

Directive 2010/63 also has staying power. It provides for its own review, in 2017, so that it will be able to keep pace with scientific and technological advances. "Were it to be abolished, we would go back to the previous situation, which was much worse in terms of animal protection," says Grossetête.

In fact, a complete ban on animal testing would have tremendous negative consequences for the development of new medicines and patients' access to them, she believes. "There are cases when the use of animals simply cannot be avoided," Grossetête stresses.

All major medical breakthroughs over the last century have been dependent directly or indirectly on scientific research involving animals, she notes. "We should not be naive; I prefer to see animals used for research here in Europe, in respect of the 3Rs and ethical evaluations, rather than in other countries where even the simplest standards of animal welfare are not abided by," Grossetête says.

efpia
European Federation of Pharmaceutical Industries and Associations

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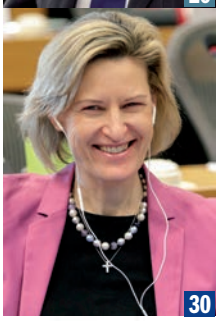

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EDITORIAL TEAM

General editorial enquiries
Tel: +32 (0)2 741 8221
Email: newsdesk@dods.eu

Managing Editor
Brian Johnson
Tel: +32 (0)2 741 8221
Email: brian.johnson@dods.eu

Deputy Editor
Desmond Hinton-Beales
Tel: +32 (0)2 741 8220
Email: Des.Hinton-Beales@dods.eu

Editorial Assistant
Jon Benton
Tel: +32 (0)2 741 8228
Email: jonathan.benton@dods.eu

Julie Levy-Abegnoli
Tel: +32 (0) 2 741 8219
Email: julie.levy-abegnoli@dods.eu

Commissioning Editor
Rajnish Singh
Tel: +32 (0)2 741 8225
Email: rajnish.singh@dods.eu

7th Floor, Rue du Trône 60,
Brussels 1050

PRODUCTION

Head of production
John Levers
Tel: +44 (0)20 7593 5705

Design
Matt Titley
Max Dubiel

ADVERTISING AND SPONSORSHIP SALES

Publishing Director
Grant Hewston
Tel: +44 (0)20 7593 5547
Email: grant.hewston@theparliament.com

Sales Manager
Sandra Fernandez
Tel: +44 (0)20 7593 5545
Email: sandra.fernandez@dods.eu

Sales
Monica Barbosa
Tel: +44 (0)20 7593 5544
Email: monica.barbosa@dods.eu

Andrew Waddell
Tel: +44 (0)20 7593 5548
Email: andrew.waddell@dods.eu

Nick Rougier
Tel: +44 (0)20 7593 5688
Email: nick.rougier@dods.eu

Alexsandra Stanisavljevic
Tel: +44 (0)20 7593 5554
Email: Alexsandra.stanisavljevic@dods.eu

Alex Paraskeva
Tel: +44 (0)20 7593 5708
Email: alex.paraskeva@dods.eu

Roisín Lynch
Tel: +44 (0) 20 7593 5573
Email: roisin.lynch@dods.eu

Alfia Fazylova
Tel: +44 (0)207 593 5594
Email: alfia.fazylova@dods.eu

Ausrine Juskeviciute
Tel: +44 (0)207 593 5643
Email: ausrine.juskeviciute@dods.eu

Subscriptions
Tel: +44 (0)1778 395 035
Email: dodssubs@warnersgroup.co.uk

www.theparliament.com

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Less is more

Later this week the European commission will unveil its new better regulation package. Thanks to a handily leaked 'draft' version some of us spent the bank holiday weekend scanning the document for any signs that Messrs Timmermans, Juncker and co may be thinking more about deregulation than better regulation. Whatever your views on this often overlooked issue, there's no doubt that the fight against "red tape" is one that often divides EU policymakers.

Legislative harmonisation, long a utopian dream of EU federalists now has a potential dark side, thanks in part to the reducing regulation debate surrounding the TTIP agreement with the term 'harmonisation' being seen as big business shorthand aimed at labelling EU rules and regulations as 'onerous' and 'burdensome' rather than 'protective' and enlightened.

So are these fears justified? Are the better regulation plans designed, deliver better rules for better results or are they an elaborate smokescreen supporting a deregulation threat to European democracy? Unsurprisingly, commission first vice-president Frans Timmermans tells our readers in this issue that better regulation is about making sure the EU delivers on its policy objectives. "Before putting forward a new proposal, we must really ask ourselves, 'is this legislation really needed at European level?'", says the Dutch commissioner, who is no stranger to the world of 'fitness checks' and regulatory scoreboards.

Key to Timmermans plans is his proposal to create a new regulatory scrutiny board to oversee the results of impact assessments on new legislation. He argues that although it is parliament and council's prerogative to amend commission proposals, "it sometimes feels like the commission is trying to design a horse… but by the end of the legislative process it ends up looking more like a camel". This and his comment that he wants to ensure that major amendments to legislative texts "are properly assessed, so that we can be satisfied that the EU institutions have reached a well-informed decision," could well be seized on by some as the opening salvo in a battle to control the European parliament's power of scrutiny. Perhaps it's no coincidence that the opening lines of Timmermans' leaked draft communication are, "The commission is determined to change both what the union does, and how it does it."

Let battle commence. ★

Brian Johnson is managing editor of the Parliament Magazine

ON THE COVER | Better regulation

Commission first vice-president Frans Timmermans kicks off our cover story feature on the EU's regulatory fitness and performance (Refit) programme. The Dutch official, and president Jean-Claude Juncker's right hand man, says, "Better regulation does not aim to deregulate; rather it means making sure we deliver on all our policy objectives, and do so in the most efficient way possible."

Also writing is parliament's rapporteur on the Refit stae of play and outlook Sylvia-Yvonne Kaufmann, who points to the fact that "According to the commission, EU countries are responsible for one third of administrative burdens, due to inefficient implementation of EU laws." For the S&D deputy, a reduction in Europe's bureaucratic burden would also help tackle "Brussels bashing".

See pages 26-34

Successful disaster prevention must begin with local approach

The new Sendai framework for disaster risk reduction must be translated into national and local actions, writes **Elisabetta Gardini**

Since 1980, natural disasters caused by climate change have increased by 233 per cent. In the past decade alone, they have resulted in the deaths of over 700,000 people, with 1.4 million injured, 23 million made homeless and €1.2 trillion in economic losses. In recent years, the Hyogo framework for action has served as a valuable tool to improve disaster prevention at global level. Adopted in 2005 and due to expire this year, it has helped reduce risk around the world by providing an international mechanism for management advice, coordination and partnerships. Nevertheless, when it comes to disaster risk, the work is never over, as the recent earthquake in Nepal has tragically reminded us.

Lok Thapa with his niece Akin among the rubble of his collapsed home caused by last month's earthquake in Nepal

With this in mind, it is a political imperative to revise and renew the Hyogo framework. I was part of the EU delegation to the third world conference on disaster risk reduction which took place in Sendai, Japan, on 14-18 March. Overall, we achieved a satisfactory result, although some grey areas remain. The 'Sendai framework for disaster risk reduction 2015-2030' was adopted at this conference and highlights that in order to reach our goals and boost the capabilities of developing countries there needs to be a substantial increase in international cooperation, as well as the involvement of all possible stakeholders.

"When it comes to disaster risk, the work is never over, as the recent earthquake in Nepal has tragically reminded us"

The international community's open commitment to multilateral cooperation was one of the conference's most promising and relevant achievements, but it is difficult to predict how well this will be carried out. Throughout the conference, many encouraging words were spoken and many pledges considered. Now, we must do our best to guarantee that the Sendai framework does not remain empty words but is instead concretely implemented by both developed and developing countries based on best practices.

As I explained during a ministerial roundtable on reducing disaster risk in urban settings, the most innovative and effective concepts and tools which are included in the European civil protection mechanism – fsuch as the notion of 'resilient community' – should be taken into account when indicating the methods to follow in a disaster-resilient world. Identifying best practice is a good starting point, but whether the Sendai framework is strong enough to ensure a more disaster-resilient future will also depend on its successful translation into national and local actions. For this reason, our ability to 'think small' and/or 'think local' is extremely important. An unconditional obligation in the next few years will be to provide local authorities and actors with the tools to carry out our ambitions. This means fully integrating them into the decision-making process – from the collection of information to national crisis management platforms – and supporting the emergence around the world of volunteer organisations based on their capacity to manage crises in a given territory.

The EU delegation fought very hard to include its ambitions in the new post-2015 framework. We must pursue further improvements and keep in mind that the real work on the post-2015 global agenda has just begun and Europe must continue to maintain its leadership.

This year's European civil protection forum on 'partnership and innovation' takes place in Brussels on 6-7 May, and will be a fantastic opportunity to discuss ways in which to improve our cutting-edge systems, strengthen cooperation and use innovative technology to serve our citizens. ★

Elisabetta Gardini (EPP, IT) is a vice-chair of parliament's delegation for relations with Mercosur

etpg

the european test publishers group

COPYRIGHT, RESEARCH, SCIENCE AND POLICY: **THE PSYCHOMETRIC TESTING EXAMPLE**

Psychometric testing highlights key issues for copyright policy and its impact on European science, research, social and economic policies.

THE IMPORTANCE OF TESTING TO EUROPE

Reliable, scientifically based psychometric testing underpins reliable, standardised and fair assessment which improves education, mental and physical health provision, careers guidance, social inclusion and productivity. Bad tests damage EU citizens and organisations in all these areas. The European Test Publishers Group (ETPG) is a not-for-profit trade association, set up 25 years ago to build on advances in the evidence-based measurement of psychological characteristics where Europe continues to be the world-leader.

THE SITUATION

Because of the nature of tests (they often comprise simple sets of questions delivered in on-line environments), copyright abuse is particularly rife in the area. This affects the ability of researchers to fund their work; influences authors' income (and many authors are academics); may reduce the money available to create new tests and, quite specifically, affect those clients and patients tests are designed to help. Use of out-of-date unlicensed tests, low quality stimulus materials etc. affects results and therefore treatment regimens and life-changing decisions. These issues are not confined to testing.

WHAT ETPG HAS DONE AND CAN CONTRIBUTE

The ETPG has spent the last three years concentrating on this issue. As membership of the group has spread across Eastern and Western Europe group members have reported many issues, ranging from the misuse of existing editions of tests to the continued use of old editions of assessment which measure inaccurately. Illegal tests are often introduced and presented in university education as trustworthy measures, thus creating misconceptions among the next generation of practitioners. We have also found that internet-sourced, public domain instruments without robust research underpinnings are sold for use as proper clinical tests.

We realise that there is a need to strike a balance between

*the needs of clinicians, psychologists, teachers, managers and other users, researchers

*the rights of publishers, test developers and authors

*the very important responsibilities we bear to the pupils, patients and workers who take tests.

To do this, we need to consider latest developments in copyright thinking such as creative commons and developments in the IT field. ETPG is creating a more proactive and educational role in advising on these issues.

In an ongoing series of sessions at European scientific conferences, ETPG members have adressed the issues with scientists, authors, psychologists and practitioners. The ETPG has also started to address the issue of the continued use of illegal versions of tests with professional bodies, particularly in the former Communist countries of Eastern Europe.

The European Test Publishers Group was founded in 1991 and now has members in over 20 European countries. The group comprises leaders of the members businesses, many of whom are psychologists and many of whom have experience publishing in other areas: research journals, academic books and on-line information. The group's knowledge is local, national and European and covers both IP theory and practical experience over legal action in copyright areas.

www.etpg.org

or contact Ian Florance ian.florance@outlook.com , +44 7966509390

Single market and digital single market are one and the same

The EU's digital single market still suffers from the same accessibility barriers it did a decade ago, writes **Catherine Stihler**

Despite the fact that the EU's last copyright reform took place back in 2001 some of our legislation has yet to truly join the 21st century. Later this week, however, the European commission is due to publish the first draft of its digital single market strategy, and in the autumn European digital economy and society commissioner Günther Oettinger is expected to present a proposal on copyright reform. Meanwhile, the European parliament is taking its own steps to outline its position on the digital single market and will assess obstacles to its completion. I have reiterated time and again that the digital single market and single market are one and the same – one cannot be complete without the other.

While the US and China benefit from a single set of laws applied within their territories, the EU has 28 sets of national legislation to contend with. Differences between national legal provisions and requirements across member states, taxation systems, consumption habits, as well as linguistic barriers, all hamper European competitiveness. Although 43 per cent of adults in the EU shop using the internet, online sales across borders in Europe account for just a tenth of total online sales in this region. If Europe is to remain competitive, the fragmentation of the (digital) single market must be addressed.

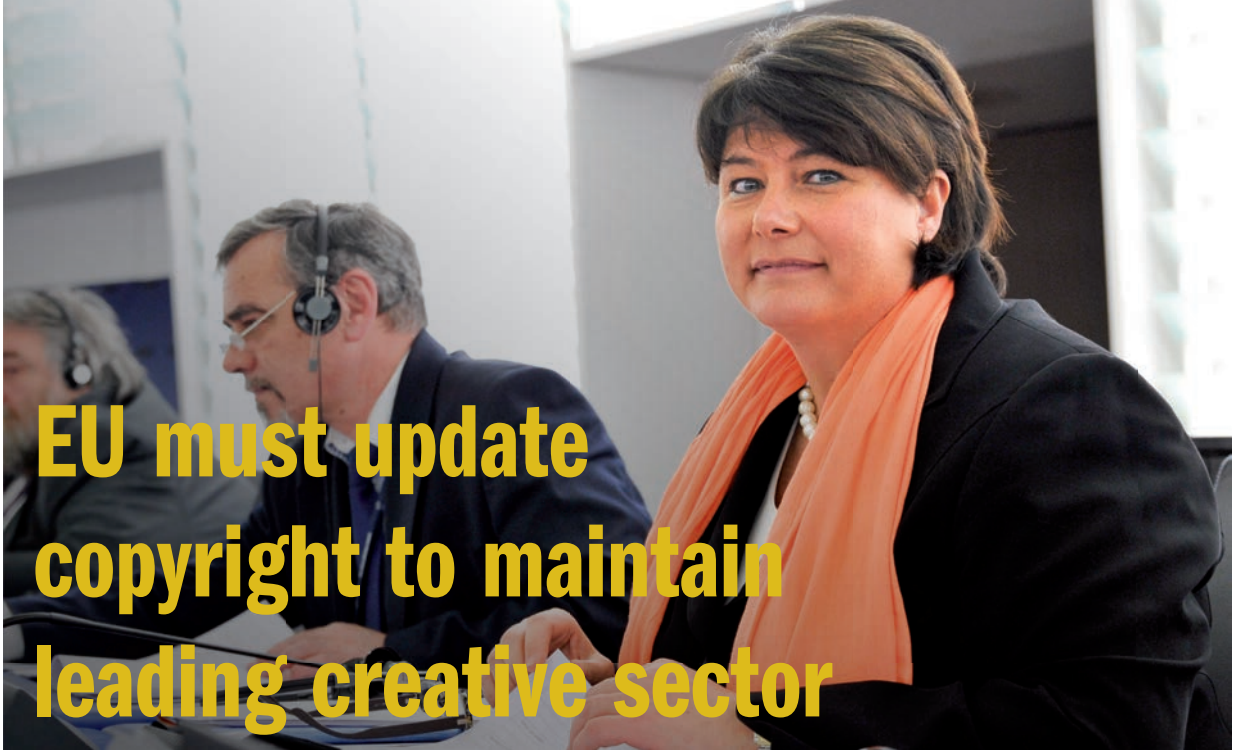
Looking at the new strategy ahead of its publication, there are several opinions within parliament that have been adopted, or are in the process of adoption. I had the pleasure of being parliament's internal market and consumer protection committee opinion rapporteur on the 2001 infosoc directive. The final committee vote took place on 24 March and the report was adopted with an overwhelming majority. During the process of tabling the report, I met dozens of stakeholders from a variety of industries and organisations, ranging from authors and publishers to consumer groups and academic researchers.

Striking the right balance on a compromise position that suits everyone will be no easy feat for the commission. However, one thing that has become clear to me is that action to address certain concerns raised since the adoption of the infosoc directive back in 2001, especially relating to the digital realm, must be taken. Things have changed rapidly since its adoption over a decade ago and copyright laws have to be updated in order to reflect the needs of our society and consumers, most of who use digital services, watch films and stream music online on an almost daily basis.

I also emphasised the important role that Europe's cultural and creative industries play employing more than seven million people while also promoting European cultural heritage. Any copyright reform needs to ensure that all categories of rights holders are protected and that they are fairly remunerated. However, problems such as territoriality, geoblocking, portability of services and interoperability must be contended with and solutions found if we are to ensure that modern copyright legislation is fit for purpose. For this reason, I urge the commission to push for a flexible and balanced framework with certain exceptions and limitations that will not harm rights holders and conforms to consumer expectations. I believe consensus can be achieved, but it's vital to maintain an ongoing dialogue between all the parties involved. ★

"Any copyright reform needs to ensure that all categories of rights holders are protected and that they are fairly remunerated"

Catherine Stihler (S&D, UK) is parliament's internal market and consumer protection committee opinion rapporteur on the harmonisation of certain aspects of copyright and related rights in the information society



EU must update copyright to maintain leading creative sector

Europe's rich cultural diversity cannot be compromised by outdated copyright rules, argues **Sabine Verheyen**

These days, quickly sharing a picture or downloading a song on the go is a regular occurrence for many people, and downloading something without paying for the content or the service is hardly viewed as illegal. For this reason, more must be done to raise awareness and promote legal content and its portability within the internal market. It is time for legal certainty. The current EU copyright rules date back to 2001 and are in urgent need of reform. The fast pace of technical innovation in recent years has meant that technology has now outgrown the legislation. Digitisation does not only make our lives easier in a number of ways, it has also led to challenges for European and national legislators.

European digital economy and society commissioner Günther Oettinger has announced that draft legislation on the topic would be presented in the autumn, and this is a very welcome move. Parliament has taken a twofold approach to copyright reform, with Pavel Svoboda working on a report on the enforcement of intellectual property rights, and Julia Reda serving as rapporteur on the implementation of the 2001 infosoc directive. This reform should be seen as an opportunity to strengthen rights and make Europe the place to be for leading creative businesses. The current debates have the potential to alter the European cultural sector in a lasting way.

This is a priority for parliament's EPP group, which is why in March, we set up a working group on the topic, co-chaired by my colleague Pavel Svoboda and I. The EPP group's aim is for the reform to create an EU-wide legal framework on sustainable copyright legislation. Only then can the cultural diversity and richness of Europe be maintained. The EU has a lead that it must capitalise on, having the most innovative and diverse creative sectors and huge potential in its languages, whether we are talking about music, film, publishing or other cultural sectors. In order to maintain this lead, copyright is the fundamental tool for ensuring that creators are incentivised and fairly rewarded for their work. Copyright legislation should, however, also consider the services and interests of all parties involved in the creative value chain. These include not only creators and consumers, but also intermediaries such as broadcasters or online platforms. A fair and balanced approach is vital for finding a copyright solution that fits today's needs.

In my opinion, there is no doubt that portability of legally acquired and legally made available content within the union should be enhanced. However, the EPP wants to reverse the current monopolisation that has taken hold of the digital market and is therefore against mandatory EU-wide copyright titles and pan-European licences for all works. Such legislation would mean a limitation of the freedom of contracts for rights holders and devaluation of rights in general. Europe has many different cultural and linguistic environments and as a result, cross-border licensing, while possible, remains an exception. Most of the content that is requested is local. The current license and exceptions system in place is applied when it is economically beneficial and if there is demand. For copyright legislation to be future-proof, exchange with experts from all parties concerned – the EPP's new working group is one example of how to set up such conversations – is key. A proactive dialogue is important for MEPs to hear the voices that shape Europe's cultural landscape and help us to protect and promote the cultural richness and diversity that make Europe as exciting as it is. ★

"The EPP wants to reverse the current monopolisation that has taken hold of the digital market and is therefore against mandatory EU-wide copyright titles and pan-European licences for all works"

Sabine Verheyen (DE) is EPP group coordinator on parliament's culture and education committee

TTIP will strengthen the EU's voice in the world

TTIP would help the EU reclaim growth and competitiveness, while maintaining its core values and protecting its businesses, argues **Jean-Luc Demarty**

At a time when Europe faces several major challenges, it is good to know that there are also opportunities. One such opportunity is the EU's current negotiation for a new trade agreement with the US – the transatlantic trade and investment partnership (TTIP). Securing a fair and balanced result is one of commission president Jean-Claude Juncker's top priorities.

These negotiations are rightfully attracting considerable attention both from parliament and the general public. An informed public debate about trade is indeed welcome, as it would underline the enormous benefits that trade has brought to Europe and its citizens. Unfortunately, the debate about TTIP includes misunderstandings and misperceptions which often have nothing to do with reality.

So, let's establish some facts, so we can continue to have a serious conversation about trade and the talks between the EU and the US. An EU-US agreement would strengthen the EU's voice in the world. In Europe, we understand the advantages of working together to develop clear and predictable rules. Decades of working together has embedded this spirit in the EU's DNA.

On the global stage, Europe remains one of the biggest economic powers. But the world is changing and in the future, 90 per cent of economic growth will take place outside the EU. As our economy becomes relatively smaller, our influence in world affairs is likely to be relatively smaller, too. Yet, the growing interdependency between economies around the world requires strengthened global rules. If the EU doesn't want to play an active role in writing those rules, we can be sure others will. The EU and the US share core values such as democracy, human rights, rule of law, regulations to protect their citizens and the environment. So, if we still want to promote our common values in the future, a transatlantic partnership will be essential.

"On average, every €1bn of extra trade means an extra 15,000 jobs in the EU"

I fully understand those who demand that we protect our European model and our values. This is also our goal. That's why we would never negotiate a deal that would, for example, lower our strict standards on food safety, health or

environmental protection. Nor will we limit the freedom of governments or local authorities to run public services, such as healthcare or education, exactly as they wish. And we will not allow products onto the European market that don't conform to EU standards. We have never done so in the past, and we don't intend to start now – neither with TTIP nor any of the other trade agreements we are negotiating. Furthermore, any agreement will uphold the way we pass laws in Europe.

> *"The debate about TTIP includes misunderstandings and misperceptions which often have nothing to do with reality"*

The most debated issue in this agreement is investment protection and the so-called investor-to-state dispute settlement (ISDS). Europe is the world's largest foreign investor and recipient of foreign investment. Millions of European jobs depend on such investments. An international system that creates confidence and legal certainty is in our interest – that is why EU governments have more than 1400 such agreements in place today, including more than 100 between themselves. Yet, the existing system is not without its flaws, and it needs to be reformed. We want to modernise investment protection and strike the right balance between the state's right to regulate and the legitimate protection of investors. That's why we have conducted a public consultation on this issue and are currently discussing the way forward with MEPs and EU governments.

The EU-US negotiations are much more transparent than any comparable trade talks. The Juncker commission and European trade commissioner Cecilia Malmström have made transparency one of their political priorities. That's why at the end of November, the commission launched a new transparency initiative, including new measures for the TTIP negotiations. One important and unprecedented measure was to publish EU negotiating proposals and make these accessible to everyone. These are the negotiating texts we gave to our US counterparts. They clearly show what we do and don't want to achieve with this agreement.

We have also set up a dedicated group of independent experts who represent the interests of different stakeholders to advise our negotiating team. Additionally, we hold regular meetings with a broad range of stakeholders, including consumer and environmental groups, trade unions and business. And, we are in constant contact with all parts of civil society so we can understand their needs, wishes and concerns.

Trade's contribution to the EU economy has never been more important than it is today. Exports outside the EU support more than 31 million jobs (which tend to be higher paid), contribute to economic growth, and help make EU firms more competitive. In 2013, the EU exported a record €2.4 trillion in goods and services. The more we export, the more jobs we create. On average, every €1bn of extra trade means an extra 15,000 jobs in the EU. The EU suffers from slow growth and 28 million of its citizens are unemployed – clearly this is an opportunity we cannot ignore.

The challenges facing Europe today are serious, and TTIP is part of a serious response to those challenges. A successful outcome of the talks will send a powerful signal that the EU and the US are ready to uphold and promote the values that have shaped our success and that we are committed to ensuring our economies remain competitive in a rapidly changing world. Let's make sure that we seize that opportunity. ★

Jean-Luc Demarty is director-general of the European commission's DG Trade

TTIP must wait until EU citizens are properly consulted

Citizens from across both Europe and the US are concerned about core issues related to the transatlantic trade and investment partnership (TTIP). The areas of concern are those that make TTIP different from a 'normal' trade agreement - or that make it very "ambitious" in commission speak. These are regulatory cooperation, the tackling of legislative and regulatory barriers to trade and the investor-state dispute settlement.

These are also the core reasons behind my group's rejection of the current TTIP negotiations. Had the deal simply been about tariff reduction with an exception for our sensitive agriculture and some annexes to harmonise industrial standards for cars, negotiations might have proceeded more smoothly.

Did the commission make the effort to find out what European citizens actually want? With this in mind we have tabled an amendment requesting the suspension of negotiations until our citizens have been fully consulted. TTIP rapporteur Bernd Lange faces a challenging task. He has my respect for presenting a report that addresses a number of the concerns being so widely discussed by our citizens and the media. If we compare Lange's draft to the previous report by his former S&D colleague Vital Moreira at the beginning of the TTIP negotiations you can see the differences. Previously, every critical nuance was rigorously suppressed, completely underestimating the public debate that has since been unleashed, with the only response a narrow plenary majority to exclude audiovisual services from the negotiations.

Today every MEP is faced with this debate in his or her constituency, which is reflected in the record number of 14 committees requesting to contribute an opinion, and the 898 amendments tabled in the international trade (INTA) committee. People understand that TTIP is much more than a trade agreement. It could be a game-changer, affecting various aspects of the lives of EU and US citizens.

Our GUE/NGL amendments include arguments and analysis from trade unions, consumer protection organisations, economists, farmers' associations, and civil liberties groups, small and medium enterprises, as well as letters from citizens. They feel that the negotiating mandate received by the commission from member state governments in charge at that time goes too far and that many of those regulations dubbed obstacles to trade are actually societal and democratic achievements.

I would like to encourage the rapporteur to listen closely to the concerns raised by so many active citizens. The GUE/NGL group will not let them down.

Helmut Scholz (DE) is GUE/NGL shadow rapporteur on recommendations to the European commission on the negotiations for the transatlantic trade and investment partnership (TTIP)

(The full version of this article is available on theparliamentmagazine.eu)

Can ETS reform stop Europe's low carbon future going up in smoke?

Achieving a low carbon economy is dependent on the EU's emissions trading scheme being made fit for purpose, writes **Sofia Kalogeraki**

As Europe's flagship tool for meeting its carbon mitigation objectives, the EU's emissions trading system (ETS) aims to efficiently reduce the entry of greenhouse gases into the atmosphere and contribute to a credible investment perspective for low-carbon investors. As such, the ETS is a key element of the energy union strategy.

However, due to a number of setbacks, including the accumulation of a large surplus of allowances, the ETS has failed to achieve its purpose of becoming the primary driver of decarbonisation in the European Union. Against this backdrop, in January 2014 the European commission proposed the introduction of a market stability reserve (MSR) with the objective of correcting the current market imbalance and preventing similar problems in the future. Negotiations on the proposal between MEPs and the member states were launched on 25 March, with a view of reaching an agreement within two months.

To broker a deal, the Latvian presidency must bridge the gap between parliament and the council's positions on the date of entry into force of the MSR, which has proven to be a most controversial issue. MEPs voted to bring the proposed 2021 start date forward to 2019. Within the council, Poland and other central European states have formed a blocking minority against the introduction of the market stability reserve in 2017 – a date supported by the UK, France and Germany – preferring to stick to 2021. In a bid to seal a deal, Latvia has now put forward 1 January 2019 as a compromise.

The fate of the CO2 allowances that remain unused due to slow uptake by new market entrants or factory closures is the second important issue. The Latvian presidency is proposing to place them in the reserve in 2020 as a compromise. This way, says the presidency, the stability of Europe's carbon market would be preserved and any artificial increase in supply towards the end of the current trading period (2020) can be avoided. It would then be the job of the European commission to revise the ETS directive in relation to those allowances and come forward with proposals for further action, if deemed necessary. The commission will propose a revision of the ETS once agreement is reached on the MSR. This review would adjust the directive on the 2030 climate and energy targets agreed by EU leaders in October last year. ★

"Let me be clear – there is no alternative to the ETS. Putting a price on carbon is the best way to cut emissions in a cost-efficient manner, incentivise businesses to further reduce their emissions, and boost innovation by helping to bring new technologies to the market"

Miguel Arias Cañete

- Almost 10 years since its establishment, the ETS remains the largest example of emissions trading in operation, encompassing over 11,500 installations across 30 countries and covering approximately 40 per cent of total EU emissions
- The ETS directive is the legal basis of the scheme and will undergo a revision this year. The revised directive will continue free allocation of carbon allowances to industry subject to international competition and also create modernisation and innovation funds. It will also introduce optional free allocation of allowances to modernise electricity generation in Poland and elsewhere
- Currently, 17 other emissions trading schemes have been implemented or are in preparation around the world. Three of these are in North America and nine in China, two of the world's major greenhouse gas emitters

Sofia Kalogeraki is a consultant for Dods EU Monitoring

Parliament votes in favour of European public prosecutor's office

MEPs have voted in favour of an interim report on the creation of a European public prosecutor's office (EPPO), which would take charge of investigating and prosecuting offences under the EU budget. Such crimes are estimated to result in annual losses of over €500m.

Rapporteur Monica Macovei explained that "the EPPO will be the guardian of our citizens' money […] and will bring cases forward before the competent courts in compliance with national legal systems, protecting taxpayers' money and restoring people's trust in the EU institutions." She said EPPO would "bring a real added value as it will be able to carry out independent investigations with streamlined procedures in cross-border cases and in full respect of the fundamental rights of the suspects in criminal proceedings".

Parliament's S&D group welcomed the vote, but their spokesperson on the issue Sylvia-Yvonne Kaufmann insisted that "the EPPO must work independently from any political influence, there must be a clear division of competence between the EPPO and the national authorities and we need a high standard of procedural rights for suspected or accused persons". Jan Albrecht, from the Greens/EFA group, pointed out that "the report […] highlights the importance of ensuring uniform and consistent rights for defendants so legal standards cannot be circumvented by picking and choosing the legal regime most favourable to a case".

From the Twittersphere

@SkaKeller Ska Keller

Juncker gets cheers for "#EUCO didnt do enough" "ending Mare Nostrum was mistake" #silenceisnotenough

@StylianidesEU Christos Stylianides

More than 5,000 deaths, more than 10,000 injured by #NepalEarthquake Our solidarity remains solid and tangible.

@GuyVerhofstadt Guy Verhofstadt

If European People's Party take their own manifesto seriously, it is high time that its leadership stands up to #Orban insulting our values

@SophieintVeld Sophie in 't Veld

@CeciliaWikstrom : Need solidarity between all EU countries. 15 receive all asylum seekers, 13 exactly zero

@EvzenTosenovsky Evzen Tosenovsky

#ILUC unfortunately further decrease to 6% of conventional #biofuels not accepted,still 7% is good news @ecrgroup

@miapetrakumpula Miapetra Kumpula-N

Morning started #ILUC. Many not happy w/ result: no binding target for advanced #biofuels I required commission to act for internal market!

@ramontremosa Ramon Tremosa

EP has voted today, by 597 to 84 votes to back, once again, a single seat for the European Parliament #EPPlenary @ SingleSeatEU

@kvanbrempt Kathleen Van Brempt

No more #plastic bags in our woods and seas. #Europe must take action urgently to cut use of plastic bags. #EPplenary

@GOettingerEU Günther H. Oettinger

Excellent news - @Europarl_EN gave green light to #ecall system. European roads & highways will be safer from 2018

@ManfredWeber Manfred Weber

We want Greece to remain a strong partner in the EU and the Eurozone. Therefore, ambitious reforms are needed @EPPGroup #reform2grow

@catherinemep Catherine Bearder

MEPs approve law to reduce use of #plasticbags in EU by 80%. Huge step forward for tackling marine litter

@JHahnEU · Johannes Hahn

With its #democratic transformation #Tunisia is a role model f.whole region! Confirmed continued #EUsupport f democr.+economic development

Commission security proposals slammed for not going far enough

European commission first vice-president Frans Timmermans and European migration, home affairs and citizenship commissioner Dimitris Avramopoulos have presented the commission's new agenda on security, which includes deepening cooperation between EU police forces and the creation of a European counter-terrorist centre. Timmermans explained that "no single member state can attack problems on its own". Meanwhile, Avramopoulos pointed out that this "is a shared agenda where everybody - member states, the commission, European agencies but also civil society and the private sector - must play their respective role in order to ensure the security of our citizens".

S&D group vice-chair Tanja Fajon said the measures "do not go far enough and are not innovative".

Ahead of the presentation, ECR deputy Timothy Kirkhope, parliament's rapporteur on PNR, called on the EU to "step up its cooperation and make sure that we are using all existing tools and new tools to tackle these challenges".

ALDE group vice-chair Sophie in 't Veld said the Liberals were "worried about the increasingly blurred lines between policing and intelligence and security tasks". And Greens/EFA group deputy Judith Sargentini warned that "stepping up mass surveillance and creating a vast data dragnet will involve enormous financial cost and divert resources from where they could be more effective: old-fashioned police work following terrorist suspects".

Europe Can Lead in Making Big Data Work for Healthcare

The arrival of big data into the health care arena is set to revolutionise not only the way in which patients will be treated, but also the way in which medicines are developed. In fact the effective use of big data will make it possible for us to address some of our greatest health concerns as a society.

In recent years, an unprecedented amount of healthcare data has been and continues to be generated within the health sector. Created by biomedical researchers, healthcare professionals, and even patients themselves, it comes to us on a variety of vehicles, including genomic sequencing machines, electronic health records and even smart phones.

Harnessing this data will help us improve our understanding of disease and pinpoint new and improved therapies more efficiently than ever before. On the horizon will be better outcomes for individual patients, an amelioration of the health of the general population and a boost for the sustainability of health systems.

The pharmaceutical industry's call for the use of big data is not based on groundless hypotheses. Proof of how big data can advance research comes in the form of a number of projects funded by the Innovative Medicines Initiative, Europe's largest public-private partnership and a joint endeavour between EFPIA and the European Commission.

Focusing on the utilisation of big data, the aetionomy project will pave the way towards a new approach to the classification of neurodegenerative diseases, particularly Alzheimer's and Parkinson's diseases, thereby improving drug development and increasing patients' chances of receiving a treatment that works for them.

The EMIF project aims to develop a common information framework of patient-level data that will link up and facilitate access to diverse medical and research data sources, thereby opening up new research avenues for scientists. To provide a focus and guidance for the development of the framework, the project focuses initially on questions relating to obesity and Alzheimer's disease.

The use of big data is also a vital means of underpinning out future as an innovative economy. The comprehensive information that can be generated will increase efficiency and effectiveness by indicating which interventions work and why, ultimately leading to more sustainable models of healthcare delivery, based on better assessment of patient outcomes.

In some way, Europe is ideally poised to capitalise big data. We possess a high level of scientific and technical talent that can ensure that big data can be generated effectively and delivered via the appropriate vehicles to those who can best use it. Moreover, we have good mechanisms in place for data protection.

At the same time, though, data generated in the healthcare arena is unique. The pharmaceutical industry recognizes this and has taken a lead in developing data-sharing platforms for researchers. What we require, though, is supportive policy, which will help to reassure patients that their data is safe and will not be open to abuse.

This is why industry is pushing for data protection legislation that will provides special rules for healthcare research. This will enable stakeholders to build a secure, responsive infrastructure and realise the potential of big data.

We also have to acknowledge that with a fragmented infrastructure and a lack of harmonisation with regards to the rules on data sharing across Europe, effective exploitation of big data cannot be optimized. What is needed to ensure we benefit from the great potential offered by big data, is a consistent European approach.

efpia

European Federation of Pharmaceutical Industries and Associations

eHealth can empower patients and improve quality of health services

eHealth would not only greatly benefit quality and access of healthcare in the EU, it would also help bring down costs, writes **Vytenis Andriukaitis**

When I worked as a doctor before entering politics, patients' records were written by hand and consultations and tests were always carried out face to face – there was no other way. Now, these practices seem old fashioned. These days, health records are kept electronically and, when necessary, a patient's health information can be shared between GPs and specialists – and even across borders – at the click of a button. Consultations can take place over the internet. Patients can monitor their own blood pressure and blood sugar levels and transmit this information to their doctor electronically. These and more innovative healthcare practices are now underway and I welcome them as part of the solution to the challenges facing Europe's health systems.

According to estimates, the number of people in the EU aged 65 and over is set to double between 1990 and 2050. Chronic diseases, which already account for 70 to 80 per cent of healthcare costs in the EU – an estimated €700bn – will no doubt continue to rise. These challenges, coupled with new innovations, high patient expectations and a widening cross-border dimension to healthcare in the EU, are putting a strain on health systems' capacities and budgets. I am convinced that the right eHealth tools are empowering for patients and that they can improve access to and quality of care. By freeing up healthcare resources – not least doctors' time – eHealth tools can help alleviate the burden on our health systems. With these benefits in mind, I want to seize the opportunities offered by the emerging European digital market and ensure that we create an environment in which practical, innovative, and cost-effective eHealth solutions can thrive.

The deployment of eHealth is the responsibility of the member states, but there are many ways the EU can support and assist. We already have EU rules and guidelines for cross-border exchange of data, reimbursement of cross-border telemedicine services and recognition of prescriptions, as foreseen by the directive on patients' rights in cross-border healthcare. In addition, we are adding value through networks, vision and financing.

The eHealth network set up under the cross-border healthcare directive provides a forum for cooperation, support and guidance for speeding up the broad use of eHealth services and solutions. Facilitating interoperability and safe and efficient handling of electronic health data across national and organisational boundaries is a key issue. The eHealth network has already adopted guidelines on cross-border exchange of patient summaries and

> *"We must ensure that eHealth solutions are legally sound as patients and data increasingly move across borders, and assure citizens that their health data will be protected"*

"According to estimates, the number of people in the EU aged 65 and over is set to double between 1990 and 2050. Chronic diseases, which already account for 70 to 80 per cent of healthcare costs in the EU – an estimated €700 bn – will no doubt continue to rise"

ePrescriptions. Such actions encourage the adoption of eHealth applications at national level.

The eHealth action plan 2012-2020 sets out a long term vision for eHealth in Europe, so we can all get the most out of digital technologies and increase the pace of change. It aims to improve interoperability between systems, increase awareness and skills among patients and healthcare professionals and to put patients at the centre of new initiatives. The plan will also ensure free legal advice for start-up eHealth businesses. A vision for mHealth – a subset of eHealth, is also being formulated. Last year, the commission adopted a green paper and ran a wide consultation on opportunities, limits and regulatory issues concerning new medical and public health practices supported by mobile devices.

The EU provides various tools to finance eHealth. Member states can use structural funds for investing in eHealth. The connecting Europe facility (CEF) will finance the implementation of the two cross-border initiatives – patient summaries and ePrescriptions. In addition, commission president Jean-Claude Juncker's €315bn investment plan will allow EU countries to invest in key growth-enhancing health projects, including on ICT (eHealth, mHealth and big data). The commission also co-finances eHealth related projects under the health programme and Horizon 2020. These include the eHealth governance initiative which supports the work of the eHealth network.

Despite the increasing acceptance and take-up of eHealth solutions in Europe, several obstacles need to be overcome for broader deployment. We must ensure that eHealth solutions are legally sound as patients and data increasingly move across borders, and assure citizens that their health data will be protected. We must also collect convincing evidence on the benefits of eHealth to foster investment.

I am pleased to witness eHealth increasingly being used alongside traditional medical practices in Europe. I firmly believe that smart use of modern technology will help the EU provide efficient, high quality healthcare for all its citizens. I will make it a priority to continue to work with my colleagues in the commission, member states and stakeholders, to maximise the potential of eHealth in the EU's emerging digital market for the benefit of EU health systems and patients. ★

Vytenis Andriukaitis
is European health and food safety commissioner

CONTRIBUTING TO THE DEVELOPMENT OF A COMPETITIVE EUROPEAN HEALTHCARE INNOVATION MARKET

Dr. Stefan Covaci, FI-STAR technical director, Technische Universität Berlin, Germany
Anastasius Gavras, FI-STAR project leader, Eurescom GmbH, Germany

FI-STAR at the NetFutures 2015 Conference, Brussels, Belgium
from right to left: **Günther Öttinger**, high commissioner Digital Society, European Commission; **Anastasius Gavras**, FI-STAR project coordinator, Eurescom GmbH; **Dr. Stefan Covaci**, FI-STAR technical director, Technische Universität Berlin

The cost of healthcare has grown and continues to grow at a higher pace than the GDP, reaching an unsustainable level, worldwide. This situation is exacerbated in Europe where the strong inclusive growth policy of its member states is combined with a demographic evolution towards more elderly. The complexity of the different forms of diseases, the variety of therapeutic means in the presence of extensive comorbidities and polipharmacy, along with the need to deliver the treatment at the point of care, form significant barriers to the deployment of an effective, efficient and profitable patient-oriented healthcare system. Smart solutions based on ICT are removing such barriers and pave the way to more innovation and smart growth in the healthcare sector.

Europe has mobilized a significant part of its industry in a Public-Private-Partnership on Future Internet (FI-PPP), which is the European programme for Internet-enabled innovation. The FI-PPP will accelerate the development and adoption of Future Internet technologies in Europe, advance the European market for smart infrastructures, and increase the effectiveness and cost efficiency of business processes through innovative services and delivery mechanisms. This initiative aims among others to deliver technologies that respond to the current societal challenges. In this context the FI-STAR project establishes early trials of services and applications in the health care sector by building on top of the Future Internet Technologies (FIWARE) developed in the first phase of the programme. The project has adopted and augmented the FIWARE specifications to create a sustainable ecosystem for all stakeholders in the global health care and adjacent markets, integrating these across supply-chains centered on the FI-STAR eHealth Platform Provider and driving change towards improvement of effectiveness, efficiency and profitability. FI-STAR delivers standardised and certified software including a trustful, secure and resilient application-delivery platform for decentralised and integrative health care, taking advantage of all Cloud Computing and Big Data benefits and guaranteeing the protection and controled sharing of personal data.

The frameworks, applications and tools produced by the FI-STAR project are currently tested, validated and evaluated through integration into the partners' cloud hosting facilities and by running a number of real clinical trials involving a rich set of health care giver and taker stakeholders in seven European countries. In addition, as part of the phase III of the FI-PPP programme, a vivid community of start-ups and web-entrepreneurs are starting using the FI-STAR platform in their development of innovative health care solutions. The 42 project partners are proactive to create awareness and uptake of the results in the healthcare stakeholder communities and achieved already their high appreciation.

FI-STAR has received funding from the European Union's 7th Framework Programme for Research and Technological Development under the grant agreement No 604691.

More information on the FI-STAR project
www.fi-star.eu
E-mail: contact@fi-star.eu

Modernization of healthcare systems:

which kind of investments for sustainable and efficient systems accessible to European citizens

17-18 September 2015
San Raffaele Hospital, Milan

Uehp
Unione Europea dell'Ospedalità Privata
European Union of Private hospitals

www.uehp.eu

Use of technology and patient-focused healthcare is a presidency priority

eHealth solutions can actively improve the health and wellbeing of patients, writes **Guntis Belēvičs**

Latvia is no stranger to the concept of eHealth. As a part of its accession to the EU back in 2004, the country had to commit to developing a national strategy for eHealth as laid out in the European eHealth action plan. Therefore, in 2005 the Latvian health ministry devised the 'eHealth in Latvia' national roadmap. The next few years were spent mapping the actual project and its architecture, along with the required technical specifications, including technical standards for eHealth. The legal framework of the eHealth information system was approved by the cabinet of ministers in 2014. In the coming years, the development of an eHealth information system will continue, in order to ensure that it becomes an important tool for higher quality healthcare and a more effective use of healthcare resources. Yet for eHealth to be successfully implemented in Latvia, it is very important that in addition to the health ministry, professionals and patients also realise its benefits.

Digital Europe has been one of the most important priorities for the Latvian EU council presidency. Rapidly growing information technologies are a source of tremendous opportunities that will boost smart, sustainable and inclusive growth for the EU, but they also come with a number of challenges that will need to be addressed in a timely manner so that these opportunities – including in the health sector – can be properly seized.

"Rapidly growing information technologies are a source of tremendous opportunities that will boost smart, sustainable and inclusive growth for the EU"

A high level conference on eHealth titled 'Me and my health – transcending borders' takes place in Riga on 11-13 May. Co-organised by the Latvian presidency and the commission, it is the first large-scale eHealth conference to be held in Latvia. The event will be a great opportunity to learn about best practices, the latest developments and planned policy changes in eHealth and mHealth, and, among many other things, generate new ideas, network and find new contacts. The overall theme of the conference is 'my health empowered by me', which reflects the central idea behind the meeting – the design and use of eHealth and mHealth solutions to support the active participation of patients in their healthcare and enhance their health literacy and communication with health professionals, with the aim of improving their health and wellbeing.

The conference will also address questions related to privacy and data protection in healthcare, cross-border eHealth services in the EU, secondary use of data for research and financing issues for the implementation of eHealth, so as to make healthcare systems more sustainable and efficient. In addition, it will be a chance to share experiences with social networking and gaming tools to increase patients' involvement and engagement in healthcare as well as best practice telemedicine and mHealth solutions. The Latvian presidency will concentrate on patient-focused healthcare, and the empowerment of these patients, addressing the use of technology to improve the quality of healthcare, innovation in eHealth and mHealth, cross-border exchange of health data and patient data protection issues. ★

Guntis Belēvičs is Latvia's health minister

EU must confront the ethical dilemmas related to eHealth

Data protection, cybercrime and the technological amplification of human potential require serious debate, says **Nicola Caputo**

As one of my priorities within parliament's environment, public health and food safety committee, eHealth is the subject of two of my written declarations – 'Ethical dilemmas in relation to technical innovation' and 'eHealth'. In addition, I have raised eHealth in numerous questions to the European commission as it holds many possibilities for bringing about decisive advances in healthcare systems within the member states of the EU.

"Its incredible range of benefits obliges the European institutions to stimulate eHealth as much as possible"

ICT technologies, which could also be linked to wearable devices, can improve care methods and life expectancy, reduce costs and management fees and help in the decentralisation of health policies. Its incredible range of benefits obliges the European institutions to stimulate eHealth as much as possible. This is a commitment I demand from the commission and the president of the council in order to safeguard fundamental rights within our public services, including the rights of the disabled, and in order to reduce the disparities in investment between member states. However, eHealth is not only a question of healthcare bureaucracy, but also represents an opportunity to question whether it is right to use new technologies to transcend the limits of the human body.

These are the guiding principles of the ideas I would like to raise in parliament. First, there are the ethical dilemmas regarding the choices made available by medical science that must be looked at in order to develop a prudent and informed eHealth policy. Should eHealth and ICT be developed alongside humanity in a supporting role, or also beyond humanity by amplifying human potential? A brain graft for treating Alzheimer's is different from one that allows a connection to the entirety of the knowledge on the internet. DeepMind – a Google company – is creating learning algorithms that combine machine learning and neurosciences. Are we progressing towards artificial intelligence? In the future, 3D printing will be capable of replacing transplants. Are we moving towards a 'bionic man'? How many of the components will still be 'human'?

Second, there is the regulation of data produced through eHealth. The online sharing of data from medical files and medical studies can stimulate research, but it must be subject to protection of the privacy of patients and their consent. A great deal of attention must be devoted to copyright aspects. This is a very active topic in the European parliament which, in my opinion, is difficult to distinguish from privacy.

I have heard that the IBM supercomputer Watson can enable amazingly accurate diagnoses and therapies, specifically tailored to the needs of patients. This is a very significant advance, but I have questions regarding privacy. There is, in fact, a justified concern that the utilisation of text and data mining on an ever-increasing volume of information, while improving the quality of services, might be used by companies in order to create monopolies and manipulate user choice, or even by governments in intelligence operations. We could consider the accumulated information – sometimes medical, but more generally all data – assembled by dominant internet companies as open data. This would then be utilisable by institutions so they can generate new services, restoring technology as a means to an end and putting eHealth in the service of humanity.

Finally, there is security versus cybercrime. Here, I am not only referring to software and associated data, but to hardware. There is a scenario where technology could be directed against humanity. What defence would we have against cyber-attacks from the deep web, where ppacemakers, insulin pumps, defibrillator implants, anaesthesia devices, ventilators connected online through the internet of things (IoT) could be unexpectedly turned off?

When considering medical applications in the context of eHealth, wearable technology, ICT and IoT, it is now up to our own consciences and the European Union to provide a response to the demanding question of where humanity begins and technology ends. ★

Nicola Caputo (S&D, IT) is co-author of a written declaration on eHealth

The European Society of Contraception and Reproductive Health

The European Society of Contraception and Reproductive Health (ESC) is a pan- European organization promoting education, training and research in contraception and reproductive health. One of the main contributors to maternal morbidity and mortality globally is lack of effective contraceptive methods and safe and legal abortion including post abortion care. Among the most vulnerable are young and unmarried women. ESC develops and supports initiatives to address the issue of barriers to contraceptive use and unintended pregnancies that occur globally, posing a challenge for both healthcare professionals and policymakers. There is consistent evidence that restrictive policy on abortion seriously endangers the health of women and children and the only cost-effective strategies to prevent unintended pregnancies are those that increase the use of effective contraceptive methods, and target equal access to sexual and reproductive health advice, information and services. ESC is involved in promotion of male contraception and emergency contraception (the "morning after methods") and in providing health care professionals evidence-based guidance in matters concerning these topics.

Currently the ESC develops and will implement a European Training Program on Contraception and Reproductive Health to serve health care professionals across Europe to improve the quality of contraceptive counseling and care to women and their partners. This comprehensive project needs financial support from the European Union and all relevant organizations that understand the importance of sexual and reproductive health for the well being of women in Europe.

ESC

The European Society of Contraception and Reproductive Health
ESC Central Office, Opalfeneweg 3, B-1740 Ternat, Belgium
Tel: +32 2 582 08 52
Fax:+32 2 582 55 15
Email: info@escrh.eu
www.escrh.eu

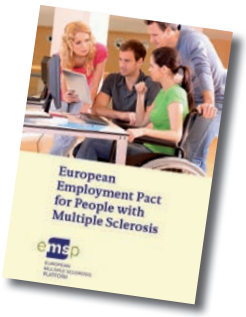
Breaking the barriers: A European Employment Pact for Multiple Sclerosis

In March this year, the European Multiple Sclerosis Platform (EMSP) launched its *European Employment Pact* for people with multiple sclerosis (MS) and other neurodegenerative conditions. A Call to Action for the *Pact* follows in May. EMSP is inviting all relevant stakeholders, from businesses to decision-makers, to pledge support.

Find the Pact at **www.emsp.org**.

Why support the Pact?

- **Business leaders** - to demonstrate their commitment for creating a healthy workplace for all. Health-focused workplace policies improve an individual's quality of life while promoting increased productivity.
- **Decision-makers** – to prove their resolve in tackling key challenges such as youth unemployment, workplace discrimination and health inequalities.
- **Patient organisations and other NGOs** - to enable the creation of a cross-border movement dedicated to improving employment for people with disabilities.



"Discrimination is a very important issue because people with MS are at a disadvantage in accessing employment. There is lack of active policies which can ensure that these people remain at work".

MEP Rosa Estaras-Ferragut (left) next to EMSP's CEO Maggie Alexander, 24 March 2015, EMSP's Pact launch in the European Parliament.

The European Employment Pact is part of EMSP's EU-funded project Paving the Path to Participation

emsp
EUROPEAN MULTIPLE SCLEROSIS PLATFORM

65% from 1,300 respondents to EMSP's 2014 survey for young people with MS said they are employed or doing voluntary work…

…but **80%** usually stop working within 15 years of the onset of the disease

700,000 people currently live with MS in Europe

70% are diagnosed during their prime working years

JOIN ACTIVE CITIZENSHIP NETWORK (ACN) FOR A DOUBLE CELEBRATION!

ACN, the European branch of Cittadinanzattiva, invites you on **May 12**:

European Patients' Rights Day

in the EU Parliament for the institutionalization of the **European Patients' Rights Day** (9 am - 1 pm) and in Rue Philippe Le Bon 46 for the opening of its office in Brussels (6 pm)

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CITTADINANZATTIVA ONLUS
ACTIVE CITIZENSHIP NETWORK
REPRESENTATIVE OFFICE TO THE EU
Rue Philippe Le Bon 46
1000 Brussels - Belgium
brussels@activecitizenship.net

HEADQUARTERS
Via Cereate, 6
00183 Rome - Italy
Tel. +39 (0)6 367 18 1
Fax +39 (0)6 367 183 33

Digital single market strategy could help healthcare transcend borders

The vital role of citizens in ensuring their own health and wellbeing is central to the theme of Europe's 12th annual eHealth week. Under the heading of 'meHealth' its focus will be on mobile health, eHealth in general and, most importantly, underlining the important role of 'us' – the citizens – in healthcare. Digital health needs reach out to citizens and empower them, not expect the citizens to make the leap on their own.

The European commission's digital single market initiative emphasises that better use of the great opportunities offered by digital technologies, which easily transcend borders, is essential. A well-functioning digital single market ensures that producers and social entrepreneurs can access finance, distribute their apps or other technologies throughout the EU and allows health systems to choose the most cost-effective and efficient solutions.

These days, our healthcare systems face several interrelated challenges. Our population is ageing, which is increasing the burden of chronic diseases, with many people struggling from multiple ailments – diabetes combined with high blood pressure and heart disease, for example. At the same time, the number of healthcare professionals is decreasing and demand for expensive technology is increasing. eHealth week has long been a forum for discussions on how these challenges can be addressed more effectively and how, instead of seeing them as burdens, they can be turned into opportunities.

The eHealth market, including mHealth, is growing fast and could potentially lead to savings of billions of euros in healthcare costs for the EU, but this will only be possible if there are changes in organisation and mentality. The creativity of Europe's best minds and entrepreneurial spirit could be unleashed if the principle of innovation were to be truly acknowledged. The effective use of electronic health records could improve diagnosis and the monitoring of treatment, while also helping reduce medical errors as digital systems can highlight contradictions, avoid repetitions and the duplication of procedures that could be painful or unpleasant for a patient. However, this will only be possible if electronic health records are shared between healthcare providers, fully respecting the privacy of patients. Moreover, telemedicine would allow regular monitoring of a condition when patients stay in the home or are travelling. This means that doctors could spot any deterioration in a patient's condition early on, when he or she is still feeling quite well, and therefore help avoid complications or unnecessary hospitalisation. Additionally, teleconsultations would improve access to healthcare for those living in remote areas, or reach patients who would not seek help in healthcare centres. Such a system would also allow experts in different member states to communicate more easily and collaborate on diagnostic and treatment processes. Mobile health would be helpful in almost all healthcare sectors, including promotion and prevention.

In April last year, the commission launched a public consultation on mHealth in the form of a green paper requesting stakeholders' views on a wide range of topics, from data protection and patient safety to the role of mHealth in healthcare systems. The results of the consultation demonstrated that the main issues which need to be addressed are related to privacy and security, and these are key to building users' trust. Consumer safety and transparency of information regarding apps were also underlined, along with interoperability and legal clarity. For Europe to maintain its leading role in mHealth, it must help its entrepreneurs overcome the obstacles they face when entering the market.

Finally, the theme of eHealth week, 'meHealth', highlights the central role of citizens in healthcare processes. This means active participation in the process, whether practicing healthy lifestyles or managing a disease. This means taking charge of our own health as well as disease – eHealth is here to support us in feeling comfortable with this responsibility. ★

Technology could transform Europe's health sector and improve access to healthcare for patients across the EU, write **Pēteris Zilgalvis** and **Terje Peetso**

Pēteris Zilgalvis is head of unit for eHealth and wellbeing at the commission's DG communications networks, content and technology

Terje Peetso is programme officer for health and wellbeing at the commission's DG communications networks, content and technology

Use of mHealth can reduce the impact of demographic change

Tackling privacy and security issues is key to empowering old people to part manage their own health and wellbeing, says **Anne-Sophie Parent**

A question certain to be raised at this year's eHealth week is whether mobile health can provide an answer to the increasing needs of Europe's ageing population. The event, held in Riga, is set to focus on the main conclusions from the European commission's public consultation on mobile health, or mHealth as some call it. eHealth is a generic term covering all ICT-enabled health services and devices that are used by health professionals, carers, funders and patients. mHealth covers all initiatives that seek to enhance the health and wellbeing of individual patients through the use of mobile communication devices, such as mobile phones, tablet computers, patient monitoring devices and other wireless devices, and are targeted at individual citizens and patients.

AGE welcomes the developments in mHealth which could help reduce costs for social protection systems and patients alike by empowering older people to partly manage their own health and wellbeing, while being more proactive in terms of health promotion and disease prevention. However, for mHealth to reach its full potential there are key issues which must be tackled. In addition to the lack of accessibility of many mTools – and their price which can deter many older people, in particular the very old, from using them – issues around privacy and security, safety and transparency require strong action to overcome older people's reluctance and concerns about mHealth applications.

Anne-Sophie Parent is secretary general of AGE Platform Europe

> *"Issues around privacy and security, safety and transparency require strong action to overcome older people's reluctance and concerns about mHealth applications"*

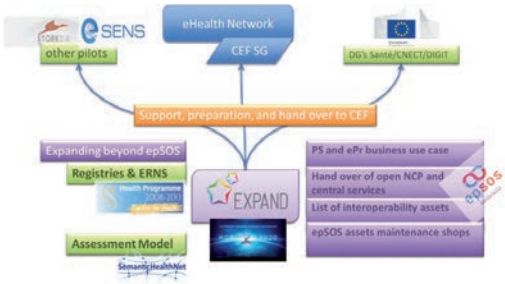
Data protection is crucial for older people using new technologies, especially when it comes to sensitive areas such as health. Although personal data are primarily used for the purpose of improving patient welfare, under some restricted circumstances data may be used for purposes other than the wellbeing of individual patients. Such circumstances require informed and documented consent but it is not always clear to older people how their data will be used, whether their data will be stored safely, who may have access to this information now and in the future and for what purpose.

Under EU law everyone has the right to protection of their personal data, but is this protection always guaranteed in practice? Looking at recent cyberattacks on highly protected databases, there are questions over whether all threats are under control. There is an obvious need for the EU to help member states improve their capacity to protect health data given the increasing deployment of mHealth across the EU. Having a clear data protection legal framework that can be applied and integrated into mHealth solutions is vital for facilitating its implementation and avoiding grey areas.

Further to ensuring an adequate legal and technical framework for protecting health data, it is also important to raise awareness among users about the potential impact of using mHealth solutions. Citizens and patients need a good understanding of privacy issues, including the right to be forgotten. It also means that data protection should be built in all mHealth applications from their inception to ensure they adopt the correct approach.

Finally, it is of the utmost importance for developers to adopt a co-creation approach, for example, involving older people in a continuous way from inception to the end of the development process to ensure the relevance of mHealth applications to those who are expected to use them. ★

EXPAND – Expanding Health Data Interoperability Services



The role of **EXPAND** Thematic Network (operating from Jan 2014 till Dec 2015) is to provide a bridge between the large scale cross border health services pilot European Patients Smart Open Services (epSOS) and the large scale deployment EU initiative Connecting Europe Facility eHealth Digital Service Infrastructure (CEF eHealth DSI).

EXPAND is supporting both the eHealth Network subgroups consolidating needed information and assets (e.g. legal, organisational, semantic and technical) and the Member States by establishing a co-operation platform towards the upkeep of cross border health services.

EXPAND has gained significant knowledge about the requirements of the "asset recipients", the profile that project assets currently have and what may be required by others (future users) for adaptation, implementation and regular operations.

EXPAND is addressing these topics focusing on assets' preparation and sustainability for CEF (taking into account progress in the policy and standardization domains since the epSOS closure), and learning and consolidating knowledge about the manifold frameworks, limitations in applicability of assets beyond a pilot, and other restricting or enabling aspects. **EXPAND** work also envisages potential implications of future expansions to other priorities of the eHealth Network and Directive 2011/24/EU.

EXPAND work is focusing on assets' collection and usability, as well as on the actions needed to support, prepare and enable Member States to reap the benefits of safe and secure cross-border care.

EXPAND
Expanding Health Data Interoperability Services

Project Coordinator Contact
Henrique Martins
henrique.m.martins@spms.min-saude.pt
www.expandproject.eu
Twitter: @EXPANDproject

SPMS EPE Serviços Partilhados do Ministério da Saúde

GOVERNO DE PORTUGAL
MINISTÉRIO DA SAÚDE

European Association for Predictive, Preventive & Personalised Medicine

Dr. Vincenzo Costigliola
President

Prof. Dr. Olga Golubnitschaja
Secretary-General & Editor-in-Chief

EPMA is the global leader in Predictive, Preventive and Personalised Medicine (PPPM) represented in the EU and altogether in over 40 countries worldwide. Professional sections, Institutional members, National and Advisory Boards collaborating together represent the robust structure and excellent scientific and technological platform of the Association – see the article recently published online [Golubnitschaja O, Costigliola V and EPMA (2015) **EPMA summit 2014 under the auspices of the presidency of Italy in the EU: professional statements.** EPMA J. 6(1):4].

For the paradigm shift from delayed reactive to predictive, preventive and personalised medicine, a new culture should be created in communication between individual professional domains, the doctor and patient, and all the stakeholders including policy-makers. This is a long-term mission in personalised healthcare utilising a spectrum of ICT / eHealth instruments available and to be developed in the field.

Under the EPMA-umbrella, the consolidated professional forum is extremely effective – see the highly accessed ***EPMA Journal*** (PubMed-indexed), **www.epmajournal.com** and ***Book-series*** "Advances in PPPM", **http://www.springer.com/series/10051** which is the world-leader in PPPM-relevant education.

EPMA is open for collaboration with other leading European and global professional networks which are kindly invited to attend ***EPMA World Congress 2015*** in Bonn, Rheinische Friedrich-Wilhelms-University of Bonn, Germany, September 3rd-5th. More information, please find here **www.epmanet.eu**

Refit measures will make sure that EU rules deliver tangible benefits

EU laws must be aimed at improving the lives of citizens and businesses, says **Frans Timmermans**

The new European commission is determined to change not only what the EU does, but how it does it. Citizens and businesses, in their day-to-day lives, need to see that we are there to serve their interests and offer solutions to issues that governments are unable to handle alone. We must restore their confidence in our ability to deliver and the better regulation agenda is key to that. Better regulation does not aim to deregulate; rather it's about delivering our policy objectives in the most efficient way possible. This month, the commission will present its new better regulation package, with a set of measures for delivering better rules for better results.

"Better regulation does not aim to deregulate; rather it means making sure we deliver on all our policy objectives, and do so in the most efficient way possible"

We in the college must constantly scrutinise ourselves and never hesitate to be self-critical. Before putting forward a new proposal, we must ask ourselves questions such as, 'Is this legislation really needed at European level?', 'Will this make a significant contribution to creating jobs and fostering a sustainable economy?' or, 'Will we create more or fewer burdens for small business?' We will continue as we have begun with our work programme for 2015, focusing on the things that really need to be done through the EU and making sure they are done well.

Applying the principles of better regulation will ensure that measures are well designed and deliver tangible benefits

"The commission is just one part of the institutional triangle, and we must work together with parliament and council to achieve our shared goals of a better law-making system. That is why we will propose an interinstitutional agreement on precisely this topic"

for citizens, business and wider society. A new regulatory scrutiny board, which will include members from outside the commission, will help us get it right by closely examining our impact assessments as well as performing major retrospective analyses.

But the commission is just one part of the institutional triangle, and we must work together with parliament and council to achieve our shared goals of a better law-making system. That is why we will propose an interinstitutional agreement on precisely this topic. I have had very fruitful conversations with parliament's conference of presidents and with the general affairs council. I see great interest in this ongoing work from all three institutions and I'm very optimistic that we can reach a positive outcome. One of the important things we must decide on is how to improve impact assessment s in the legislative process. As I've said to MEPs and stakeholders, it sometimes feels like the commission is trying to design a horse, but by the end of the legislative process it ends up with something that looks more like a camel.

Of course, it is up to the council and parliament to amend legislative proposals. However, I want to ensure that any major amendments that are being made to legislative texts are properly assessed, so that we can be satisfied that the EU institutions have reached a well-informed decision.

We must also listen more – the commission wants citizens, businesses and civil society across Europe to provide feedback on any aspect of EU law, at any time. We want to know how EU law affects them, and how we can make it work better. They are the ones who live with our laws, and they are the ones who can tell us where our rules fall short, and I hope also where we do well. With this in mind, we will propose new ways to improve stakeholders' ability to give us their input.

Finally, it is essential that every single measure in the EU's rulebook is fit for purpose – modern, effective, proportionate, operational and as simple as possible. EU policies should be reviewed regularly: we should be honest and accountable about whether we are meeting our policy objectives – about what has worked well and what needs to change.

Our regulatory fitness programme (Refit) has the potential to be a prominent political tool. All commissioners see the importance of reviewing our existing legislative stock, and I hope this opportunity to improve our laws will attract as much political attention from outside the commission as does the introduction of new laws.

Politicians have a natural tendency to focus on new initiatives. However, citizens judge the EU not just on its new political initiatives, but also on whether existing laws are delivering their expected benefits on the ground. ★

Less is more: Facts and figures

- 74 per cent of Europeans believe the EU generates too much red tape
- Almost 200 Refit actions are being implemented
- More than 6100 legal acts have been repealed since 2005
- 53 legislative proposals were withdrawn in 2014 and almost 300 since 2006
- According to the commission, the administrative burden for businesses has been reduced by more than 26 per cent in 13 priority areas since 2007, leading to savings of more than €32bn per year
- Since 2010, over 350 impact assessments have been carried out before proposing new legislation

Source: ec.europa.eu/refit

Frans Timmermans is European commission first vice-president for better regulation, interinstitutional relations, rule of law and charter of fundamental rights

Reducing EU bureaucratic burden will help tackle Brussels bashing

Simplifying the EU policymaking process would send a message that people's voices are being heard, argues **Sylvia-Yvonne Kaufmann**

According to Eurobarometer statistics, nearly three out of four EU citizens think Brussels creates too much bureaucracy. In response, in 2012, as part of its 'better regulation' drive, the European commission launched the regulatory fitness and performance (Refit) programme, aimed at making EU legislation more efficient and effective. A high-level group, led by former Bavarian minister-president Edmund Stoiber, has been advising the commission and has already made recommendations on reducing the administrative burden across the EU. Refit touches upon all European legislation, which is scrutinised in full by the college. Based on this scrutiny proposals are submitted for simplification, withdrawal, and even suggestions that some legislation be fully repealed. Particular attention has been paid to small and medium-sized enterprises (SMEs), as they feel most affected by the regulatory burdens caused by European laws.

Better regulation is an important priority for parliament's legal affairs committee, which has decided to draw up an own-initiative report on the subject. As parliament's rapporteur, I believe it is important to support the commission in its efforts to take the recurring complaints of too much 'Brussels bureaucracy' seriously. At a time when euroscepticism is gaining popularity across member states, it is vital for the European institutions to prove that not only are they listening to citi-

"According to the commission, EU countries are responsible for one third of administrative burdens, due to the inefficient implementation of EU laws"

zens' concerns, they are also willing to address them and make changes. Ultimately, this is about regaining popular support for the European project.

I believe a fitness programme for EU laws is the way forward. European legislation needs to be precise, but it also needs to be as un-bureaucratic and effective as possible. Using this thinking, European laws would be easier to implement in member states, and the administrative burden for citizens and businesses would be reduced. However, this should not lead to sensible regulations at EU level being called into question. What matters is quality, not quantity. As such, it is particularly important to have a coherent process throughout the cycle of a legislative initiative, from its introduction, consultation, impact assessment and enforcement through to its implementation.

When examining legislative proposals, I believe the commission's impact assessment board needs to act in a more balanced way. EU legislation is not a simple cost-benefit analysis. A proper assessment process must put the economic, social and environmental consequences of legislative proposals on an equal footing, while also taking into account what impact they have on the internal market or on EU integration. It is worth pointing out that European laws usually replace around 28 separate national standards. They are often more effective, create common European added value and ultimately mean less bureaucracy than a patchwork of national regulations.

In principle, I believe that the commission's focus on the interests of SMEs though the proposal of regulations adapted for these companies is worthy of support. These businesses are the backbone of our economy, and they should be able to concentrate on their core activities rather than preoccupying themselves with unnecessary administrative tasks. However, two thirds of the EU's working population is employed by an SME. This is why it is important to me as a Social Democrat that SME adaptation tests under Refit are not carried out at the expense of standards covering the protection of workers, consumers or the environment. Reducing bureaucracy must not become synonymous with deregulation.

"Reducing bureaucracy must not become synonymous with deregulation"

As part of Refit, a check by member states on the implementation of EU legislation is a requirement. According to the commission, EU countries are responsible for one third of administrative burdens, due to inefficient implementation of EU laws. It therefore makes sense to look beyond Brussels towards Europe's capitals, and carefully pinpoint unnecessary bureaucracy at national level, known as 'gold-plating'. Consequently, I would argue that the member states should be identifying when they have created more administrative work than planned by the EU. In order to achieve greater transparency and a closer relationship with citizens, the general public should be made aware of who holds responsibility for what. This would probably also go some way to eliminate any 'Brussels bashing' tendencies, although we should not forget that member states have a right to set higher national standards than those laid out in any EU directive. However, this, of course, should not be confused with overregulation.

Last but not least, the reduction of bureaucracy should be of major concern to all European stakeholders. Carrying out fitness checks on EU legislation is without a doubt the correct approach. However, it is equally important to ensure that social and environmental achievements in Europe are not compromised under the guise of reducing bureaucracy. This would only further jeopardise the trust between Europe's institutions and the citizens of the union. ★

Sylvia-Yvonne Kaufmann (S&D, DE) is parliament's rapporteur on the regulatory fitness and performance programme (Refit): state of play and outlook

Refit is a chance to prove EU's commitment to better law-making

Both MEPs and the commission have long worked to reduce the EU's administrative burden, but the job is not finished, says **Angelika Niebler**

European citizens are tired of an EU that is too far away, too bureaucratic, with too much regulation on too many details. The European commission, with its 'new start for Europe', is determined to change that. Commission president Jean-Claude Juncker wants an EU that is 'bigger and more ambitious on big things, and smaller and more modest on small things' and he certainly has my full support in this regard. The principle of subsidiarity is the building of a strong foundation for the functioning of the EU and has long been included in the treaty. In areas which do not fall within the EU's exclusive competence, the union shall act only if the objectives of the proposal cannot be sufficiently achieved by the member states – either at central, regional or local level.

Back in 2006, the commission began its ambitious work on reducing regulatory burdens created by European legislation, therefore making the EU more attractive, especially for its small and medium sized enterprises. The key is to 'think small first'. In its action programme, the commission – together with EU member states – made a commitment to reducing administrative burdens by 25 per cent before the end of 2012. A high level group led by former Bavarian minister-president Edmund Stoiber was set up as an independent body to advise the college. Needless to say, it was very successful, with the reduction of administrative burdens resulting in annual savings of €33.4bn, including €18.8bn in savings on invoicing costs and €6.6bn on annual accounting requirements.

Angelika Niebler (DE) is parliament's EPP group shadow rapporteur on regulatory fitness and performance programme (Refit): state of play and outlook

Parliament has consistently called for more work to be done on improving EU law-making and cutting red tape. In 2011, I was parliament's rapporteur on guaranteeing independent impact assessments, and the house now has a unit dedicated to this, in order for independent impact assessments to be carried out on legislative proposals. It is now well-established and the committees often go to it for advice on topics such as the cost of 'non-Europe', European added value and the economic, social and environmental impact of the legislation that features on parliament's agenda.

At the end of 2012, the commission published its first communication on the so-called regulatory fitness and performance programme (Refit). The goal back then remains unchanged today – to eliminate unnecessary regulatory costs and to ensure that the EU legislative body is fit for purpose. However, more work needs to be done. Parliament's EPP group fully supports the college's 2015 work programme, which demonstrates Juncker's commitment to achieving his goal – only 23 new initiatives have been proposed for adoption this year, compared to an average of over 130 new initiatives featured in the annual work programmes of the previous commission.

The EPP group will call for a thorough but swift renegotiation of the 2003 interinstitutional agreement on better law-making. Since then, the Lisbon treaty has come into force and we must take into account the new legislative environment we find ourselves in, and bring the agreement up to date with the better law-making agenda. The group will also reiterate its request to strengthen the independence of the impact assessment board and for it to report directly to European commission first vice-president for better regulation, interinstitutional relations, the rule of law and the charter of fundamental rights Frans Timmermans.

Lastly, we would like to highlight the 'one-in-one-out' approach that has already been introduced in some member states, and call for a 'sunset clause' in new legislation, so that it has an automatic end date unless a revision comes to a different conclusion. After all is said and done, we will see how committed the commission truly is to better law-making. ★

Businesses and citizens deserve say in reducing regulatory burden

There needs to be an assessment mechanism in place to measure Refit's success, writes **Sajjad Karim**

The regulatory fitness and performance programme (Refit), launched by the European commission in December 2012, is important for jobs and growth in Europe, as it aims to make EU law lighter, simpler and less costly so that citizens and businesses benefit. Some might argue that this puts into question the EU's policy objectives, but this is far from true as it seeks more effective ways to achieve them. Under Refit, the commission regularly screens the entire stock of EU legislation for burdens, inconsistencies and ineffective measures, and identifies corrective action accordingly. The aim is to make sure that policy objectives are achieved and the benefits of EU legislation are enjoyed at the lowest cost and with the least administrative burden possible.

The Refit: state of play and outlook report published last June is the most recent of its kind and has a number of key aspects. The annual statement of costs to business of regulation is one of these, which asks for the commission to produce a statement of this kind. This is essential if we are to tackle burdens, because without a measure of how we are adding or subtracting costs or burdens, we cannot judge our success. We can be hugely successful in cutting existing burdens, but if we are only replacing them with new costs and regulatory hurdles, we are not doing a good job for businesses and our citizens. We have also improved impact assessments significantly. There is now the possibility to comment on draft impact assessments, including via a notice and comment approach, and also extending this to secondary legislation. This is most important in ensuring that our legislation tackles the problems identified, in the least burdensome and most effective way possible. This is particularly important when we talk of secondary legislation, which is having an increased impact on the internal market and which until now has not always been properly assessed. By improving the transparency and evaluation of all proposals coming from the commission, draft laws will correspondingly be improved, as too often we have poorly justified and poorly designed proposals coming to the European parliament.

> *"I believe involving the actual 'end users' of legislation – the businesses or the citizens who have to comply with the regulations - in assessing them and suggesting improvements - is a powerful idea that can help us really tackle the problems that exist in our regulatory environment"*

One of the most crucial achievements to date is our burden reduction target, which we have asked to be set at 25 per cent for a stakeholder forum. This is an idea that I am very supportive of and that already works well in Denmark and was replicated recently by the UK government. I believe involving the actual 'end users' of legislation - the businesses or the citizens who have to comply with the regulations – in assessing them and suggesting improvements - is a powerful idea that can help us really tackle the problems that exist in our regulatory environment.

Finally, I am very pleased that there was a majority for the 'comply or explain' principle to apply here, which will help make sure that the commission treats these ideas seriously and obliges the college to respond if they don't take on the forum's recommendations. This way, the commission will be transformed from another 'talking shop' into something that could be very useful in our drive to cut red tape – a key aim of the Conservative party in the EU. ★

Sajjad Karim (UK) is parliament's ECR group shadow rapporteur on regulatory fitness and performance programme (Refit): state of play and outlook

The VOX-Pol Network of Excellence (NoE) is a European Union Framework Programme 7 (FP7)-funded academic research network focused on researching the prevalence, contours, functions, and impacts of Violent Online Political Extremism and responses to it.

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Refit should not serve as a smokescreen for deregulation

A key initiative of this European commission is the regulatory fitness and performance (Refit) programme. Refit aims to simplify and rationalise the EU's regulatory framework so that it is straightforward, clear and predictable for businesses, workers and citizens. Its purpose is to reduce bureaucracy, eliminate regulatory burdens, simplify and improve the form and quality of legislation, and to do all of this while fully respecting the treaties and, particularly the principles of subsidiarity and proportionality.

In its communication, the commission outlines the state of play and progress made so far in the implementation of Refit, while also proposing a series of new initiatives for further simplification. Administrative and regulatory burdens have already been reduced in various sectors, for example through electronic invoicing of VAT or in matters concerning accountancy and financial information, as well as legislation on chemical products, patents, public contracts and road transport.

Parliament's environment, public health and food safety (ENVI) committee – which I chair – recently expressed its opinion on Refit and reaffirmed some important political points. The EU certainly needs to reduce bureaucracy and eliminate superfluous regulatory burdens. However, Refit should in no way serve as a smokescreen for deregulation under the pretence of 'reducing bureaucracy', especially when it comes to the environment, food safety and health. This is why the commission was strongly criticised for its withdrawal of the waste package, though parliament has sought to understand the motivation behind this decision. MEPs are awaiting a new proposal on the circular economy, which is expected to be published before the end of the year, and are ready to get to work in order to achieve a truly ambitious reform. The ENVI committee opinion has also requested that nutritional profiles not be included in the planned European standards for regulating information provided on food labels, particularly promotional messages. The 'nutrition and health claims' regulation required the commission to define by means of nutritional profiles which foods may be used in nutritional or health advertising claims, but six years after it was put forward, the commission has made no provisions along these lines. I agree with the ENVI committee's vote, because I believe that it is now too late for the commission to introduce the definition of nutritional profiles. It would also serve little purpose, given that consumers already have all the information on the nutritional value of food available on the market under the 'food information to consumers' regulation.

Refit touches upon other topics that fall under the ENVI committee's competence, such as the withdrawal of the proposed soil directive, the proposal for access to justice in environmental matters, the ongoing Natura 2000 supervision of the protection of birds and habitats and general food legislation. There is also the new valuation and supervision of carbon capture and storage, CO2 emissions from cars and light commercial vehicles and legislation on chemical substances, other than the registration, evaluation, authorisation and restriction of chemicals regulation.

On all of these points the parliament, and more specifically the ENVI committee, wants a clear, simple and effective regulatory framework that is able to combine firm and robust protection of the environment, as well as the safeguarding of consumers and their health while being careful not to adversely affect the competitiveness of our businesses in these difficult times. ★

Giovanni La Via wants a clear, simple and effective regulatory framework that protects health, consumers and the environment

Giovanni La Via (EPP, IT) is parliament's environment, public health and food safety committee opinion rapporteur on the regulatory fitness and performance programme (Refit): state of play and outlook

"Refit aims to simplify and rationalise the EU's regulatory framework so that it is straightforward, clear and predictable for businesses, workers and citizens"

New legislation must demonstrate the added value of EU involvement

Othmar Karas says EU better regulation objectives need to be matched by better implementation at national level

The sheer torrent and complexity of EU legislation has created a negative image of bloated bureaucracy in the eyes of the European people. Studies have revealed that 74 per cent of Europeans believe that the EU creates too much bureaucracy and, ultimately, this view is based on poorly communicated laws, which are ostensibly seen as diktats from Brussels.

This is not how the EU functions and it should not be perceived this way. Over the past decade, 6,100 legal acts have been repealed and 300 proposals rejected after they were proven to be outdated, no longer appropriate or superfluous. Last year the commission announced the withdrawal of 73 legislative proposals, and this was officially confirmed a few weeks ago. The new college has set better legislation as one of its core objectives, and is designing its structure accordingly. Since 2012, the regulatory fitness and performance (Refit) programme has identified specific measures for the simplification, reduction and repeal of legal acts and the withdrawal of proposals which have been debated for far too long and are wasting useful resources. However, in no way does intelligent regulation mean deregulation or dropping high standards.

I was the opinion rapporteur on Refit for parliament's internal market and consumer protection committee. My proposals, consisting of 11 core requirements for better EU legislation to strengthen the internal market while benefiting both citizens and companies, were adopted on 17 March. I believe EU legislation must show clear added value and avoid fragmentation between member states. For each European law put in place, a national law should be abolished. Costs of compliance should be estimated well in advance, in addition to the costs of failing to act at the European level. Policymakers must also bear in mind the 'think small first' principle, and compulsory small and medium-sized enterprises (SMEs) tests should be carried out as part of each impact assessment. The 'Your Europe' portal was designed to provide specific information for SMEs, but it is out of date and should be upgraded into a usable EU information tool. We should be thinking about how EU information can be more clearly presented and targeted to the right audiences.

A third of the administrative costs associated with EU law arise from individual state implementation measures, which is something that needs to be considered. 'Gold-plating' – when member states give European directives additional powers while transcribing them into national law – should be avoided. Impact assessments should be required as standard for delegated and implementing acts if they are expected to have a considerable effect. Moreover, the interinstitutional agreement on 'better regulation' should be revised and there must be a mutual exchange of proven methods. We measure the costs of not being in Europe, so compliance costs should also be made measurable. Implementation of EU law at national level should be evaluated, reported and measured by the member states. We must use and further develop proven methods, while anyone wanting to get involved in a consultation requiring specialist knowledge should not be being discouraged by convoluted language. The high level group on better regulation – formerly known as the Stoiber group should also continue its work, under the responsibility of commission first vice-president Frans Timmermans, and be given an independent advisory mandate. Hearings and consultations with stakeholders should be timely, transparent and clear, and qualitative analysis methods should ensure that minority views are also taken into account.

While the commission has pledged further fitness checks on legislation, and this should be commended, what Europe also needs is the coherent use of existing EU law and stringent implementation of directives in the member states. ★

"A third of the administrative costs associated with EU law arise from individual state implementation measures, which is something that needs to be considered"

Othmar Karas (EPP, AT) is parliament's internal market and consumer protection committee opinion rapporteur on the regulatory fitness and performance programme (Refit): state of play and outlook

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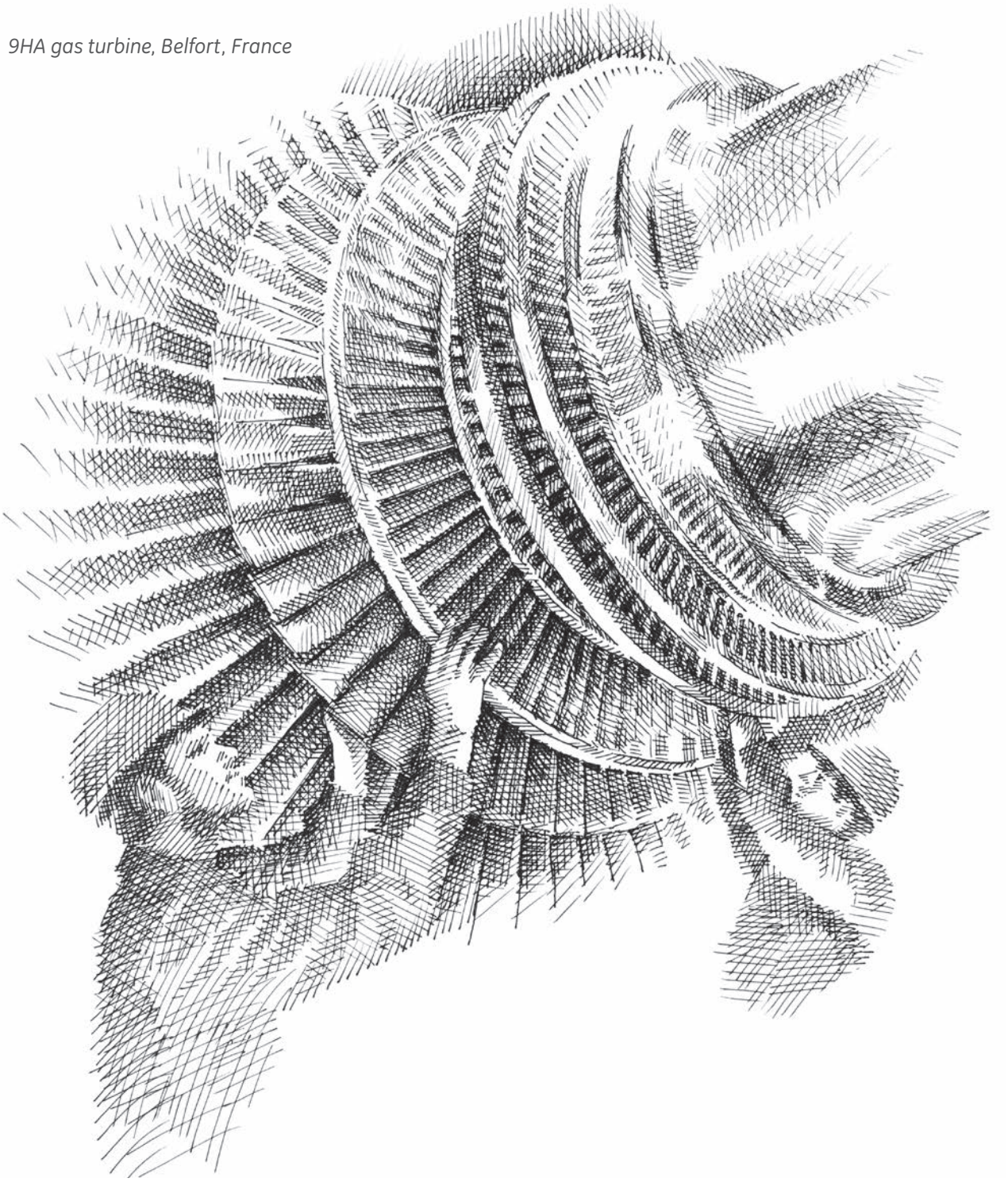

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