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**EU energy commissioner Günther Oettinger on improving safety standards for Europe's offshore oil and gas exploration**

*"Offshore energy production is a very complex and risky business"*



### Clinical trials

Glenis Willmott, Paola Testori Coggi, Peter Liese, Michèle Rivasi and Cristian Buşoi

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### Inside:

Antigoni Papadopoulou on therapy for heart attack patients, Roberts Zile on Latvia joining the euro and Claudiu Ciprian Tănăsescu on tuberculosis

**Plus:** eSkills, EU defence policy and UK-EU relations

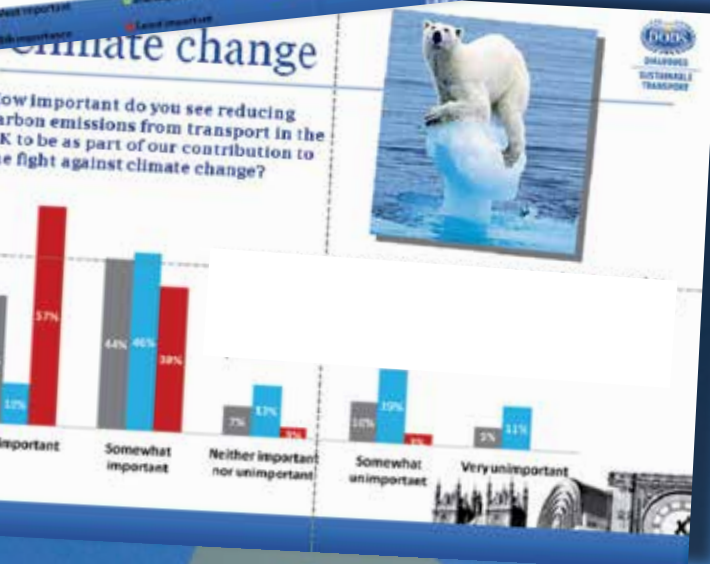


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# Averting the crisis

In Europe we live in times of crisis. A crisis of confidence, in the ability of our common institutions to produce results and meaningful policies, and a crisis of faith, that our continent cannot overcome its economic problems and deliver a future of hope and prosperity for all.

This is why legislation, such as the recently approved directive on the safety of offshore oil and gas prospecting, is a good step in mending the breach of confidence with European citizens.

With this directive, we allow for all countries that want to embark on the effort to explore the wealth of the oceans to do it in a safe and responsible way. Fair, common, clear rules attract investors, they shouldn't, and they don't, scare them off. No license would be granted if a company cannot prove it has the financial means to correct potential catastrophic damages. Prospective investors will be asked to submit reports on the real dangers of installation, offer emergency intervention plans and protection schemes for workers. Whistleblowers, the brave women and men willing to risk their lives and careers to report safety breaches and potential accidents, will be protected. Our member states will be required to draw detailed emergency plans on what should happen when disaster strikes, who should be responsible for each part of the response, and who should ultimately pay for the damage. The European maritime safety agency will also play a bigger role in the equation. And, as should happen in a union forged on democracy, local populations, trade unions, national authorities, safety experts – everyone potentially affected – will have a say before any drilling takes place.

What we are looking for in Europe is arguably a tough sell. We want to exploit the wealth of our lands and seas, but without compromising on our commitment to preserve them for generations to come. We want to attract capital and investment from around the world, but without betraying the social conventions that Europeans have learned to expect from government. With this directive, the union will deliver on all ends. By achieving this, we create an example for future legislation in all policy areas, moving us closer to bridging the divide between the union and its people. ★

**Dimitrios Droutsas is a vice chair of parliament's industry, research and energy committee**

## ON THE COVER | Licensed to drill

European energy commissioner Günther Oettinger kicks off our special report on offshore oil and gas, writing that “safety concerns all European citizens”. He argues that member states should ensure the highest safety, health and environmental standards when it comes to offshore oil and gas. “If a major accident took place in Europe, the damage caused by an oil spill would probably not be limited to the country where it occurred,” he adds. Ireland's communications, energy and natural resources minister Pat Rabbitte, writes, “Ultimately, our goal as policymakers in the area of offshore exploration activity is to improve safety in extremely challenging environments.” Parliament's rapporteur on the draft directive for offshore oil and gas Ivo Belet, meanwhile, warns that “Adequate emergency response is vital to limit the consequences of any spill or accident.” **Licensed to drill, page 33-34**



# A growing threat

Tuberculosis is a growing concern that requires coordinated member state, EU and worldwide action, writes **Claudiu Ciprian Tănăsescu**

**I**ulian, a former Romanian tuberculosis (TB) patient, who died from the disease last spring, said, “When you have TB you have two options: you take the TB pills and get better, but starve, or you work and have to come back to the sanatorium. So, it’s a lose-lose situation. It’s a disease where people in society stay away from you, because they know you are sick.”

Unfortunately, TB has several other facets. Not only does TB cause stigmatisation for patients, it causes illness and death, and if not properly treated leads to very high costs for society. In the EU alone the fight against TB costs €15m per week and €750m per year in medical costs.

This cross-border health threat kills 1.4 million people each year worldwide and seven people per hour in the European region, representing the second leading cause of death from an infectious disease.

In 2011, 8.7 million people were infected with TB worldwide. The global burden of TB still remains high, but most worrying is the growing number of drug resistant (DR) TB cases, some of which are now being transmitted directly from person to person. Multi drug resistant (MDR) TB and extensively resistant TB are much more costly and difficult to treat. Curing an MDR TB case can be 100 times more expensive than a ‘normal’ TB case.

If we provide more than €750m per year for the disease, over 90 per cent of MDR TB patients will be detected and provided with adequate treatment by 2016. If not, progress will scale back and we will witness an increase in all forms of TB.

A clear signal for immediate action in the EU should be given by the five EU member states (Romania, Bulgaria, Estonia, Lithuania and Latvia) that are among the top 28 MDR TB high burden countries worldwide, registering a very low treatment success rate. Romania’s treatment success, for example,

is much below that of Kazakhstan, or even the Democratic Republic of Congo.

Political commitment and financial support from decision makers are key if we are to control this major public health threat. Countries need to put in place strategic action plans to fight TB in order to save money and improve the state of health of the population.

To attain a better control of TB we have to make invest-



*“Not only does TB cause stigmatisation for patients, it causes illness and death, and not properly treated leads to very high costs for society”*

ments in research and development into new tools – effective vaccines for all populations, new medicines, early and appropriate treatments, cost effective diagnostic methods and resistance detection tools – and to dispose of fully funded national TB programmes. Personally, I see four major steps towards achieving these above mentioned objectives.

First, at the EU level, the commission should back up, both financially and politically, the implementation of the World Health Organisation (WHO) action plan on DR TB for the period 2011-2015. If implemented correctly it will save 120,000 lives and €2.92bn in the short term. It is not just the European commission, but individual countries who have to take a stance to the growing TB threat and increase the domestic funding allocated to this problem.

Second, the commission and EU member states should commit the necessary resources to the 2013 replenishment of the global fund to fight

Aids, TB and malaria. The global fund alone provides 80 per cent of the international funding for TB. WHO estimates that 118 low and middle income countries will face a funding gap of at least €0.92bn per year for TB for 2014-2016.

Third, awareness has to be raised not only among decision makers but also among the general public. For this reason the public-private partnerships and the engagement of community groups should grow in importance, providing the tools necessary for the NGOs to reach populations otherwise out of reach by governmental programmes.

Fourth, the commission should address the roughly €750m funding gap in R&D for TB by significantly increasing its funding for health research and particularly poverty related diseases in the next research framework programme.

If action is not taken now we might lose control over a major health problem. Not dealing properly with TB translates in an increase of antimicrobial resistance and growing national costs for health. WHO estimates a rise of up to two million DR TB cases up to 2015. For this reason, urgent action from the EU and endemic countries worldwide is needed to cope with this growing, cross-border health threat. ★

Claudiu Ciprian Tănăsescu is a member of parliament's environment, public health and food safety committee



# Access to life

The EU must coordinate its activities and work to improve access to life saving therapy for heart attack patients, writes **Antigoni Papadopoulou**

It was a great pleasure for me to host a discussion on 'Improving access to life-saving therapy for acute heart attack patients' on 24 January at the European parliament, in collaboration with the European Critical Care Foundation and the 'stent for life' initiative. The event brought together EU policymakers, cardiologists, medical researchers, industry partners, patients and other concerned stakeholders who exchanged views on recent research findings, best practice, and ways to overcome obstacles to improve access to life saving therapy for patients suffering acute heart attack.

There are many gaps and barriers across EU member states when addressing heart attack patients' access to adequate care. We are all aware of cases of people losing their lives because of gaps in emergency transport systems, gaps in emergency response times or inadequate infrastructure to ensure reliable intervention therapies without delay. A personal incident of a sudden death within my family has made me more aware and sensitive to how important it is to act immediately and to rely on expert intensive treatment to save lives. The victim of the incident was my husband who suffered cardiovascular disease (CVD) problems. He has fortunately survived from the sudden death episode, thanks to an immediate resuscitation intervention, prompt arrival of the ambulance and immediate transfer to the intensive care unit. During the following years, we went from one hospital to another for various operations, met doctors in several countries, and learnt about different health systems.

Access to safe and quality treatment varies widely among member states and regions and areas of the EU, despite the increasing uptake of technology and the impact of eHealth. What is more surprising is that these inequalities are not solely related to national economic variables. They may be caused by differences in the organisation of the healthcare systems, such as emergency transport systems or hospital networks. As a member of parliament's women's rights and gender equality committee, and having discussed the matter with others, I believe that gender disparities also exist in the access to best treatment for heart attacks

because of under-diagnosis for women and, consequently, under-treatment.

I am aware that chronic diseases constitute the largest health threat to the EU population, with CVD identified as the number one killer in Europe, killing more people than all cancers together and having an economic impact on health systems exceeding €110bn annually, according to the European commission's data. There is a pressing need for more effective therapies, taking these into consideration as well as the expected rise of CVD because of the ageing EU population. During the debate, we listened to scientific evidence, shared experiences and ideas and collected views on ways to act. I strongly feel that we need to coordinate actions and work together in order to improve access to life saving therapy for heart attack patients.

As an MEP, I am strongly committed to working towards increasing awareness on the issue and will help in any way possible to overcome barriers and imbalances, thus saving lives. I would be very pleased if other MEPs, patients and civil organisations would like to join in and exchange ideas. During the 2013 European year of citizens, we must all act together to make Europe a better and safer place to live. Together we can achieve more. ★

Antigoni Papadopoulou is rapporteur for parliament's civil liberties, justice and home affairs committee on the 2013 European year of citizens

*"There are many gaps and barriers across EU member states when addressing heart attack patients' access to adequate care"*



# United in diversity

Many minority languages are under threat of extinction in the EU, which is why it is vital to ensure that they are safeguarded, writes **François Alfonsi**

**O**n 21st January last year I submitted my draft report to parliament's culture committee. The aim of this report is to plead the case for the European parliament to play a vital part in protecting and raising the profile of European languages under threat of extinction.

Three decades or so ago, the European parliament had already expressed concern over the issue of minority languages. Indeed, one of the first tasks of the culture committee has been the creation of the European charter for [regional or] minority languages of the Council of Europe, which was appended to the Lisbon treaty. While parliament has, therefore, already played a positive role in the past, it is vital that it should return to the task since the situation has deteriorated, particularly over the last 10 years.

There are several hundred languages within the European Union, each of which is an integral part of the cultural identity of Europe. However, European cultural diversity within the European Union can be seen to have been eroded at an increasingly faster rate, hand in hand with a relaxation of government policies, whereas Europe's structural mission should be to ensure that its languages and cultural diversity are safeguarded.

In 2009, Unesco published the third edition of its endangered languages atlas, which records an alarming finding with regard to the European Union: there are several dozen languages under threat of extinction in Europe. While some countries, such as Finland, take pride in the fact that for over 20 years, a highly fruitful political initiative has been undertaken in the case of the Saami language, other states refuse to accept the cultural diversity which exists within their borders.

The report which I have undertaken to prepare focuses more specifically on languages threatened with extinction. This is indeed an area where the issue is a matter of urgency and where Europe's cultural heritage is under direct attack. The European par-

liament must be capable, once again, to trigger a reaction, a realisation throughout the European Union.

A new multiannual (2014-2020) planning programme is due to start. Political will must, therefore, be revived, as must a dialogue with the commission, to ensure that support for minority languages is not conspicuous by its absence from this new planning period, as it regrettably was from the 2007-2013 planning schedule.

As part of the preparation of this report on endangered languages, I organised a workshop on 20 March last year, at the European parliament, to which about 15 representatives of the areas affected by this problem were invited, thus allowing them to confront our speakers: Jonathan Hill, from the European commission, Meirion Prys Jones, from the network to promote linguistic diversity, Christopher Moseley from Unesco, Adina Nichifor, representing the Council of Europe, as well as Markus Osterlund, representing the Swedish assembly of Finland.

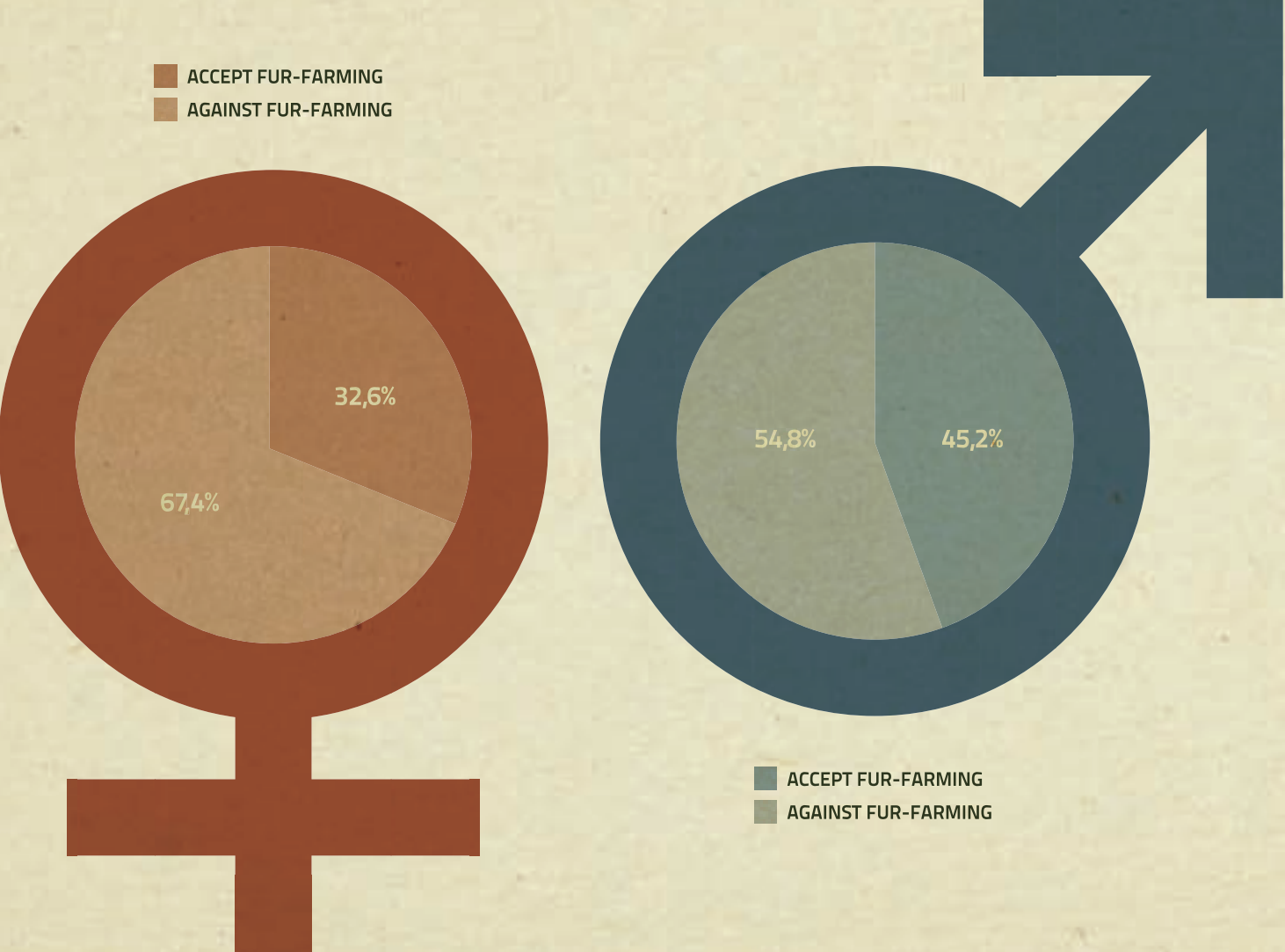
The communities and groups responsible for this linguistic heritage should, indeed, be given more assistance and encouragement in the implementation of good practices. Through this report, I intend to ensure that the European Union stands as a guarantor for what is true cultural and linguistic diversity within its borders. As clearly stressed by Jonathan Hill when he spoke at the workshop, cultural heritage must not be sacrificed on the altar of economic profit. ★

*"I intend to ensure that the European Union stands as a guarantor for what is true cultural and linguistic diversity within its borders"*

François Alfonsi is parliament's rapporteur of endangered European languages and linguistic diversity in the European Union

# MEN AND WOMEN'S PERSPECTIVES ON FUR

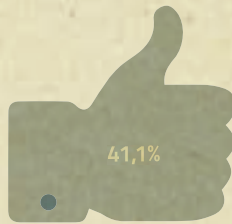
European men and women's feelings and opinions about fur and fur farming differ in quite a few areas. Men are more inclined to find fur farming acceptable than women, but at the same time more women than men wear fur. 22,8% of European women have bought a natural fur product for themselves, while this is the case for only 15,9% of the men.



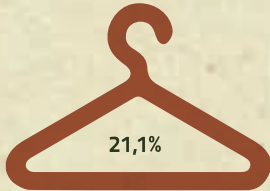
Source: Pan-European survey conducted by independent market research company Ipsos in 2013. The survey was conducted in the UK, the Netherlands, Denmark, France, Spain, and Poland.



## LIKE FUR



## WEAR FUR



## HAVE BOUGHT A NATURAL FUR PRODUCT OF ANY KIND FOR SOMEONE ELSE AS A GIFT



## HAVE BOUGHT A NATURAL FUR PRODUCT OF ANY KIND FOR HERSELF/HIMSELF



## Opinion

In every issue of the Parliament Magazine, we voice an opinion about the European fur sector.



**PIA HANHIMÄKI**

Project Manager, Finland

### *Do you wear fur?*

Yes I do. I wear vintage fur, and I have a coat and a scarf. It is not for ethical reasons I wear vintage; it is only about the price.

### *How do you see the future of the fur farming sector?*

Fur is big in fashion and I believe fur will remain a popular product. As long as prices are high they will be a demand; fur is still classified as a desirable luxury product. If people turn against fur farming there is a risk that China will take over the production in the future. In Europe we have stricter legislation and the control is better. I believe the animals will be better taken care of if the production stays in Europe. Restrictions of the current fur production would also have a remarkable impact on the economy in Europe.

*Full interview at [furinformationcenter.eu](http://furinformationcenter.eu)*

## Right now

The welfare assessment protocols for fur farmed species – the Welfur protocols – are being printed just now, and will be introduced to the members of the European Fur Breeders' Association in Sirmione, Italy on the 11th April. The protocols are based on the methodology of the European Commission's Welfare Quality® project, and will be the foundation of common, science-based welfare standards on fur farms across Europe.

The European Fur Information Center is founded by EFBA (European Fur Breeders Association) and IFTF (International Fur Trade Federation) to create awareness and knowledge about the fur sector in Europe based on openness, transparency and verified facts.

*Please contact us, if you need any information about the European fur sector.*

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**EUROPEAN**  
European Fur Information Center

# Value for money?

Financial aid given by the EU to Europe's eastern neighbours is increasingly coming under the spotlight. **Martin Banks** reports

In the four years since the EU launched its eastern partnership policy nearly €3bn has been allocated to six countries, with the European neighbourhood and partnership instrument funding going to Moldova, Armenia, Georgia, Ukraine, Azerbaijan and Belarus. In terms of financial assistance per capita, the bulk of the €2.8bn went to two countries, Moldova and Georgia.

According to EU enlargement commissioner Štefan Füle, such funding is designed to help support democratic and economic reforms in these countries. "This support goes not only to the reform efforts of the governments," he says, "but is also designed to increase the role of the civil society which has an important part in the transformation."

Since the eastern partnership (EaP) was launched in 2009 in Prague, it has funded a range of programmes ranging from roads and education to improved water facilities and climate change mitigation projects. In Moldova, for example, EU funds have been partly used in the fight against corruption and on structural reforms. The country has been particularly successful in implementing economic reforms and in 2010, 2011 and 2012 boasted one of Europe's fastest growing economies.

The level of funding for the post-2014 seven-year spending period is currently uncertain, pending the outcome of the ongoing discussions on the EU's long-term budget. Financing the EaP came under the spotlight at a public hearing organised by the budgets committee in parliament on 20 March.

Some MEPs, such as senior Polish deputy Jacek Saryusz-Wolski were particularly scornful of the EU's EaP policy, condemning what he called the "self satisfaction" of the European commission and external action service (EAS) towards the six recipient countries. Saryusz-Wolski, a former government minister in Poland, said that the €2.8bn allocated to the six countries had yielded "meagre results". "The problem is that EU aid to eastern partnership countries is too widely dispersed for the policy to be a success. There is a whole multitude of projects which, as we heard at the hearing, no one seems able to follow or understand," said Saryusz-Wolski, a former foreign affairs

committee chair. Similar concerns were voiced by Dutch member Jan Mulder, who said, "The €2.8bn going to these countries is an enormous amount of money and there needs to be a lot more scrutiny on how it is being spent."

Another speaker, Olaf Osica, director of the centre for eastern studies in Warsaw, expressed some reservations, saying that "in four years the policy had failed to produce any tangible political or social results", warning that, as such, the EU "runs the risk of losing momentum" in the region.

However, Marcus Cornaro, deputy director general at the commission's DG Devco, defended the EaP, telling the hearing that the EU was "doing quite well" in addressing issues about transparency and accountability in the way EU funding to the six countries had been spent.

His comments were partly echoed by Richard Tibbels, an EAS divisional head, who, while accepting that funding was "considerable", said the EU was keen to push ahead with closer cooperation with the six, particularly with those EaP countries which could demonstrate a "real commitment" to the reform process. Tibbels also pointed out that the EU was set to sign trade association agreements with five of the six countries and raised the possibility of financial "incentives" in the post-2014 spending period for those EaP members which were shown to have made "significant" progress in implementing reforms. ★

*"The €2.8bn going to [EaP] countries is an enormous amount of money and there needs to be a lot more scrutiny on how it is being spent"*

*Jan Mulder*



# Modern times

Moldova has progressed towards becoming a modern European country, but remains realistic about the challenges it still faces, writes **Iurie Leanca**

**M**oldova is a small country, with big ambitions. We have much to do and in many ways we have been left behind in comparison to other central European states. The support of the European Union and the dream of re-joining the European family is helping to galvanise reforms in our country which are changing lives in Moldova for the better.

We have recently completed negotiations with the European Union on an association agreement and deep and comprehensive free trade area. These arrangements will be good for Moldova, but they will also be good for EU citizens who will benefit from greater access to our goods and services and for EU businesses seeking to invest.

The changes necessary to meet European standards have dovetailed and supported our own domestic reforms. As a European commission progress report on the eastern partnership noted on March 20, we have made significant strides in improving citizens' rights, health and education. There have been major reforms to our agriculture and, against a difficult backdrop, we have also managed to stabilise our economy, achieving cumulative GDP growth of 15 per cent over the last three years.

These reforms, also supported by the EU, will help Moldova become a better functioning state that will in the future fully contribute to European stability and prosperity. We have also put in place a robust system of transparency dictating how EU funds are spent and we work extremely closely with the European commission on these issues.

We remain realistic, however, about the challenges we face. Corruption, in particular, continues to blight our progress. In the last three years, we have risen 11 places in Transparency International's corruption perception index, from 105 to 94. This is still unacceptable, but it shows that we are making progress and we remain determined to go further still.

It is true that we are a major recipient of EU aid and support and it is right that people would wish to remain vigilant on how this is spent. But much of this funding is allocated to

roads, schools and infrastructure that is making a tangible difference to people's lives.

With European Union support we are implementing the integrated border management system, which contributes to a strengthened migration control to the benefit of ours and the EU's citizens.

It is important to note that, as recently as 2009, we faced civil unrest following disputed elections, but as Radoslaw Sikorski, the Polish foreign minister, said in February, "I first visited the republic of Moldova in the period of street riots. Frankly speaking, I thought then that you were heading towards the future of a failed state. Now, Moldova is taking firm steps towards accession to the EU."

We have come a long way in a short period of time and the support of the EU, both financial and moral, has, and is, playing a key role in our journey towards becoming a modern European country. ★

*"It is true that [Moldova is] a major recipient of EU aid and support and it is right that people would wish to remain vigilant on how this is spent"*

**Iurie Leanca** is deputy prime minister and minister of foreign affairs and European integration for Moldova





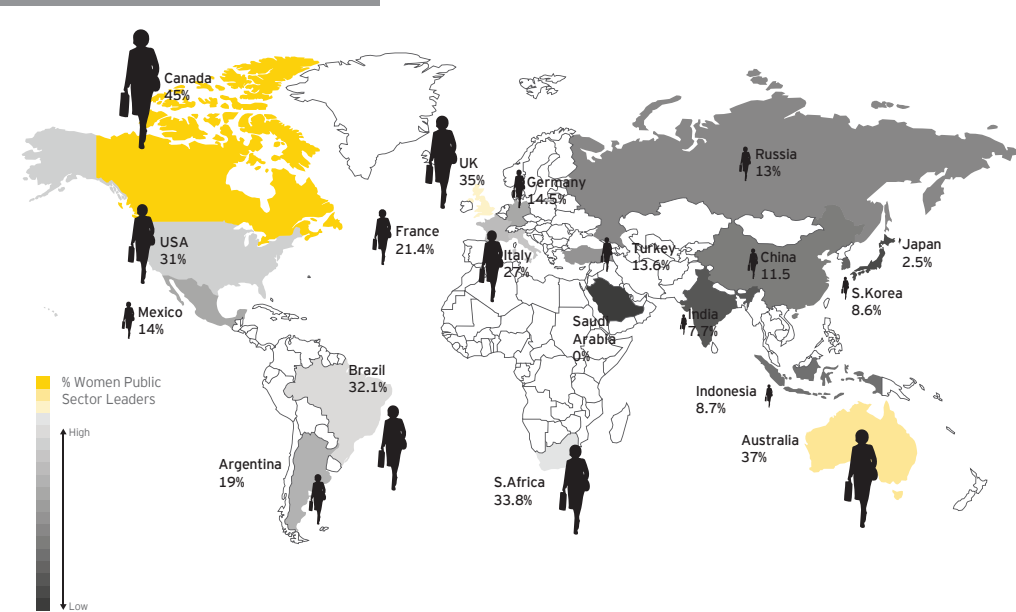
## Innovative leadership calls for the diverse perspectives of both women and men. And not just in the boardroom.

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# Balancing the books

Women are still facing ‘invisible barriers’ and preconceptions of their ability, a Parliament Magazine roundtable has heard. **Ruth Marsden** was there

**T**he benefits of a balanced gender mix across the public and private sector may be widely accepted, but women still face “invisible barriers”, a Parliament Magazine roundtable debate has heard. The event, organised in association with Ernst and Young, brought together MEPs and stakeholders to look at the current gender balance in public sector leadership roles and the importance of women in such roles.

Uschi Schreiber, Ernst and Young’s global government and public sector leader, said, “We’ve had policies in place for a really long time, so we should have made a lot more progress.” Schreiber continued, “A long time ago we thought education was the answer. Get women into education and everything else will fall into place. Then we thought it was social policy.”

Schreiber stressed that while these policies had “helped

move things along”, there is still “much more to be done”. Women face “invisible barriers”, Schreiber argued, adding that many people, women included, hold “perceptions about what women can and cannot do”. “There are not enough female role models in senior positions to become sponsors to other women in senior roles,” she said, emphasising that women “have an obligation to look after other women”.

Schreiber also highlighted the importance of maintaining a gender balance when making important decisions, saying, “Governments are dealing with the most complex issues of the 21st century, so to not have balanced decision making is silly.”

Françoise Le Bail, director general of the European commission’s DG justice, told participants that securing an equitable gender balance “is a long-term battle and a fight we should not stop”. Things are beginning to move along in the com- ➔





*“Governments are dealing with the most complex issues of the 21st century, so to not have balanced decision making is silly”*  
*Uschi Schreiber*

**Leading by example**

Ernst & Young’s study of senior public sector roles across G20 countries shows that only four of them reached even 30 per cent representation of women in leadership roles, despite women constituting a significant part of the overall public sector workforce in many countries.

Of course, legislation and policy to address visible barriers are important to deal with equal employment opportunity, address open discrimination, safeguard maternity leave and ensure other protections of women in the workforce. However, experience also shows that legislation alone is not enough as other, less visible, factors impact on women’s progression into senior leadership roles. Cultural transformation is needed to address invisible barriers. Leaders need to send a consistent message in support of achieving greater equality at senior levels. Part of the solution is to embed accountability into performance targets, but it is also crucial to lead by example and address inappropriate behaviours and attitudes that undermine the goal of gender equality. Importantly, leaders need to be open about the fact that unconscious bias impacts recruitment, promotion and other decision making – they need to discuss it, understand its impact, measure it and put in place systems and processes to minimise it.

In my conversations with women public sector leaders, many of them feel that for themselves and their peers it is important to consider their legacy to the workplace and take on a stewardship role on behalf of other women. They are thinking about how to make their departments better for future generations and how to be a role model to aspiring women.

*Uschi Schreiber is Ernst and Young’s global government and public sector leader*

mission, she said, adding that, with the women on board proposal receiving backing, it has been a very important few months. “The vice-president [for justice in the commission Viviane Reding] actually talked to the business community the year before, saying she was happy not to legislate as long as they moved forward them-

it is a chemical board.”

Le Bail concluded, “We will continue fighting for this. We believe there is a strong economic case for having women in the private sector.”

Danish MEP Britta Thomsen told the debate that work must be done to combat “much more complicated barriers”

selves. And a year later not much had happened. Company boards which feature only 16 per cent representation by women are ‘not normal’, Le Bail argued.

Reding, the EU commissioner for justice, fundamental rights and citizenship, finally succeeded in securing adoption of the women on board directive in November last year, meaning a legally binding quota of 40 per cent of women on non-executive boards of public listed companies must be introduced by 2020. Le Bail, however, was critical of the response to the directive from businesses, saying, “The reaction we got from companies was always the same, ‘we have been looking for women but can’t find any, and if we do, they don’t have the right qualifications.’” “However, we’re targeting non-executive members,” she said, “so the profile does not have to be specialised in chemistry – for example, if



*“There is still a lot to do, not only in the public sector, but also politics”*  
*Britta Thomsen*



### It's in the genes

For the last five years we have been working very closely with many senior business women and connecting them globally through Inspire, our board network. It has become very clear to us that even the most senior women seem to share a common trait, which can fundamentally impact on their career choices.

Women are far better at promoting the abilities of others than themselves and spend more time worrying about the 5 per cent experience they lack rather than the 95 per cent they have, which ultimately prevents them from applying for a suitable role.

However, this inbuilt humility also manifests itself as several positive traits, which are now in great demand in the boardroom, such as being collegiate, good facilitators, having a more measured approach, using highly developed emotional intelligence to work more effectively.

So it's not necessarily a question of changing behaviours or acting like their male colleagues, it's more a need to recognise and be aware that women tend to overlook themselves and are often passed over by their male peers. Many women need to start using this trait of the 'humility gene' to their advantage as a key selling point.

If it is a question of confidence, then the easiest way to improve this is to join a supportive network internally or externally. We have also found that if a woman is recommended by a peer, she is far more likely to be positive about her ability to perform well in a role. So if women start to recommend each other for roles, this will also overcome the restricting impact of the 'humility gene'.

*Carol Rosati and Alexa Bailey are co-founders of Inspire*

that contribute to underrepresentation for women. Thomsen then cited the situation of female professionals in Portugal and Denmark, explaining that career possibilities for women are extremely different in different countries. "In Denmark it is much easier to become a minister than a secretary-general, but in Portugal it's the other way round," she said.

"In Denmark, we have direct elections so women can actually vote for women. The Danish parliament is filled with women – 39 per cent – and we have a woman prime minister," the S&D deputy added. "There is still a lot to do, not only in the public sector, but also politics," she said.

Carol Rosati, a co-founder of Inspire – a business network for senior board level women, said that women "should inspire each other and put each other forward for positions, rather than men". There are different things that can affect whether a woman gets a job or not, she said, adding, "Women have to help themselves."

Rosati, also the director of global recruitment consul- ➔

*"In real terms, has enough progress been made? Not really. It's still appallingly slow"*

*Carol Rosati*



*"The reaction we got from companies was always the same, 'we have been looking for women but can't find any, and if we do, they don't have the right qualifications'"*

*Françoise Le Bail*

### Striking a balance

When it comes to getting a better gender balance across both public and private sector boards it's clear that self regulation has not worked. This month the percentage of women on the boards of the UK's biggest companies has fallen (to 17.3 per cent) for the first time since the figures were compiled in 1999.

At the current rate of change it would take more than 40 years before we are anywhere near equal in terms of representation on boards and that's simply not good enough. We now need to make progress quickly.

A Leeds university business school study showed that having at least one female director on the board appears to cut a company's chances of going bust by 20 per cent, and that having two or three female directors lowered the chances of bankruptcy even further. Irrespective of size, sector and ownership, for established companies, as well as for newly incorporated companies, the risk of insolvency reduces with the presence of female directors.

We now need a stronger focus on taking action to deliver change. It is essential that we organise more training, support networks and mentoring schemes to help women get board-ready. Women need to use their personal networks to help and support other women into high level positions in the public and private sector. Companies should be given incentives to meet the 40 per cent target and where they fail then face sanctions and penalties.

In short, change is necessary in both the private and public world, if we are to strengthen the EU's competitiveness, combat the current economic crisis and create sustainable growth, all talents must be utilised in full and all voices must be heard when making decisions shaping the future of our economy.

*Arlene McCarthy is a vice chair of parliament's economic and monetary affairs committee*

tancy Harvey Nash, warned that another barrier for women is the interview panel. "If a senior woman going for a senior job is not met with a senior woman in the other side she is unlikely to get past the first stage." However, Rosati said that having asked women about quotas in the past, the majority were against imposing them on companies, but were still keen for action to be taken. "In real terms, has enough progress been made? Not really. It's still appallingly slow," she said.

Arlene McCarthy, a vice chair of parliament's economic and monetary affairs committee, concluded that, "The more gender diversity there is, the better quality the decision making will be. Also, there will be a better use of the talent pool, especially with an ageing population," the Labour MEP argued. "However, we know that it's not that easy to get women to board and executive level," she added. ★

For the video of this event go to [theparliament.com/video/](http://theparliament.com/video/)

*"The more gender diversity there is, the better quality the decision making will be"*  
Arlene McCarthy





## Providing a common framework to describe ICT competences

Given the importance of Information and Communication Technologies for the European economy and the need to promote the development of skills in this sector, common frameworks are necessary to describe the competences of ICT professionals and users in a comparable way.

The **CEN Workshop on ICT Skills** is an open platform that brings together representatives of the ICT industry, training providers, the education sector and other stakeholders. It contributes to the European Union's e-Skills strategy by producing relevant supporting standards.

The **European e-Competence Framework (e-CF) for ICT Professionals** is designed to support the development of high-quality training schemes and internationally recognised vocational qualifications. A similar framework has been created to describe the skills that are needed by ICT users.

The e-CF is already being used by a wide range of companies and organisations, many of which are also involved in the Grand Coalition for Digital Jobs (launched by the European Commission in March 2013).

For more information see [www.ecompetences.eu](http://www.ecompetences.eu) and [www.cen.eu](http://www.cen.eu)

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# A view to eSkill

Filling the growing number of ICT job vacancies in Europe is crucial for achieving the Europe 2020 strategy. **Desmond Hinton-Beales** reports

Commission president José Manuel Barroso has made clear his desire for the EU to make the transition to a “smart, sustainable and inclusive economy” as part of the Europe 2020 strategy that aims to boost the bloc’s growth over the coming decade. If this dream is to be realised, however, the EU’s competitiveness and innovative capacity must be increased and an efficient and organised use of information and communication technologies (ICT) is crucial for achieving this.

The role of ICT in everyday and professional life has increased exponentially over the past 20 years and, as yet, shows no signs of slowing. However, the EU’s ability to truly seize the opportunities presented by this rapid development in ICT capabilities is reliant on the European workforce and citizens having the necessary knowledge and skills. With 900,000 job vacancies expected in European information and communication technologies by 2015, Barroso proposed at the beginning of May a ‘Grand coalition for digital jobs’. In his announcement, the commission president called upon governments and the EU’s ICT business and training and education sectors to work together to address the gap between the growing amount of digital jobs available and the insufficient number of ICT-skilled graduates and workers.

“The grand coalition... is an essential part of getting Europe’s economy back on track and finding jobs for some of

Europe’s 26 million unemployed,” said the Portuguese official. Barroso’s comments echoed those of digital agenda commissioner Neelie Kroes when she addressed the world economic forum in Davos at the start of the year. “The digital skills gap is growing, like our unemployment queues,” she said, calling for joint action from governments and businesses to “bridge that gap”.

Barroso also praised the companies who had already agreed to sign up to the scheme. Companies who have yet to join the coalition, however, can still make a commitment up until 31 May, ahead of the presentation of the pledges at the EU’s digital agenda assembly held in Dublin in June.

One of the major issues that the coalition will look to focus on is improving the image and attractiveness of careers in ICT. The coalition will work to inform students and young professionals of the diverse range of ICT careers available, with 100,000 new ICT posts becoming available each year. Ireland’s jobs, enterprise and innovation minister Richard Bruton stressed that, “the number of ICT graduates in Europe has decreased from 127,000 in 2006 to 114,000 in 2010”, adding that the EU “cannot afford to allow European labour markets to fall behind in this way and lose job opportunities in favour of other regions of the world”. Bruton also highlighted the need to “re-skill” Europe’s workers for the many ICT positions that do not require graduate degree-level knowledge, which could be met by “short tailored training combined with work experience”. The minister said that this would allow ICT to increasingly become a “promising option” for unemployed workers. This would also be facilitated by plans to introduce a common EU certification for ICT skills, which, combined with funding and assistance, could enable the easy movement of eSkills workers throughout the EU.

At a time of high unemployment, European citizens drastically need the right skills to flourish in an increasingly digital job market. Barroso stressed at the launch of the coalition that, “If, together, we can turn the tide and fill the growing number of ICT vacancies, we will see a much wider impact across the whole economy. “We want to empower Europeans to fill the jobs that will drive the next ICT revolution,” he said. ★

*“We want to empower Europeans to fill the jobs that will drive the next ICT revolution”*  
José Manuel Barroso

# **EU INSTITUTIONS AND INSTRUMENTS NEED TO BE STRENGTHENED TO AVOID REPEAT OF CYPRUS CRISIS**

*The ALDE group reacted strongly against the proposed terms suggested by the Eurogroup of finance ministers last week, which would have made ordinary Cypriot savers pay the price for years of irresponsible lending and risky investments by the country's banks. Fortunately, the latest rescue plan agreed by the Cypriot government and EU finance ministers rectified what would have been an outright contradiction of EU law on deposit guarantees. This would have been little short of daylight robbery, and would have left the doors wide open to major uncertainty and instability for savers across Europe.*

*The rights spelled out in the EU's deposit guarantee laws should never have been put into doubt. If we want people to trust Europe, we must ensure legal certainty.*

*But the scare over Cyprus has also stressed the urgent need to establish a European banking resolution mechanism and a common deposit guarantee scheme. Such a European resolution mechanism has to be funded by the banks themselves in relation to their risk profile, not by the taxpayers in the north or the small depositors in the south of Europe.*

*This new system has to be put into place as soon as possible in order to avoid similar situations in the future. Europe cannot continue facing one state of emergency after another.*





# Monetary precision

Latvia's solid economic fundamentals and careful preparation for single currency membership should reinvigorate the eurozone, writes **Roberts Zile**

Latvia is on track to join the eurozone by 1 January 2014. At the beginning of March the government requested the European commission to deliver a convergence report on the country's readiness to join the monetary union. From the Latvian point of view, the report should be positive as the country fulfils all the eligibility criteria. To name but a few, our 2012 inflation level was 2.3 per cent and is falling, reaching just 0.3 per cent in February. At the same time, the government deficit for 2013 is forecast to be 1.4 per cent, while the debt levels are just over 40 per cent. It is clear that Latvia has done its homework and it should rather come as a surprise to most if for whatever reason either the commission or later the council of ministers say no to Latvia's accession efforts.





Fortunately, there are no signs of that so far.

There are, of course, some who worry that Latvia could repeat the same mistakes that some of the southern European countries made after joining the eurozone. Namely, that after achieving monetary union membership, interest rates in Latvia will fall, the country will be flooded with cheap credit fuelling some sort of credit bubble which will lead to, as a side effect, prices and wages rising, and the country will become much less competitive and eventually the good times will be followed by hard times in the not too distant future.

Latvia is a different case. We have already experienced the boom years as well as the difficult times that followed. The country was hit hard by the recent financial crisis. Painful and very unpopular reforms needed to be implemented. It is debatable whether the government made all the right decisions and if better alternatives could sometimes have been chosen. Nevertheless, Latvia is back on the growth path which proves that we have learned to overcome the difficulties.

In fact, Latvia has recorded the strongest growth levels in the European Union for the past two years and is likely to replace neighbouring Estonia, which

joined the euro area in 2011, as the fastest growing eurozone economy, according to a recent analysis by Ernst & Young. As such, Latvia will join the euro club as an already strong and growing economy while being part of the monetary union will help Latvia consolidate its recent macroeconomic achievements and will ensure sustainable growth levels in the future.

To put it differently, Latvia is not looking at the eurozone as a prize to be won, but – once a member of it – will appreciate the benefits the euro area offers; and to a small country there are many. During the financial crisis, Latvia was left by itself to defend its currency against attacks, while the banking sector was weakened and reduced lending. It might be politically challenging to explain to our citizens that we need to contribute to the European stability mechanism (ESM), which would also be used to bail out countries where minimum monthly salary is at least twice as high as that in Latvia. Nevertheless, when in the eurozone, Latvia and its banking sector – if problems were to arise – would benefit from help by the European Central Bank and could qualify for support from the ESM. It can also be hoped that the single supervisory mechanism will bring better banking supervision standards to Latvia, where two banks have failed during a four-year period.

The eurozone is also about geopolitical security. Being more closely integrated in the European core reduces some of the risks that could arise from direct or indirect third-country influence. However, at this point it must

also be noted that around one half of all deposits in Latvia come from non-residents – of which 80-90 per cent are from the commonwealth of independent states, according to the IMF. The trend is only going to increase when Latvia joins the eurozone, unless our financial watchdog and the government implement some much-needed measures to reverse the trend. Taxing those deposits is just one idea that could be given thought.

There are also other reforms that need to be accomplished, preferably before the introduction of euro. To single out one issue, our current tax system is vastly unfair to those earning small salaries. The minimum monthly net salary is 20 per cent below the subsistence level, yet the government has no plans to differentiate the income tax rate. Even though we do not expect high inflation after joining the eurozone, it is not in the country's interests to maintain such a regressive tax system within the monetary union.

Nonetheless, Latvia could not join the euro at a better time. Together with Estonia, and hopefully soon Lithuania, Latvia is going to be a breath of fresh air within the monetary union – a country confident about its fundamentals and ready to help in building a stronger Europe together. ★

Roberts Zile is a Latvian MEP and economist

*“Latvia has recorded the strongest growth levels in the European Union for the past two years”*



# A pragmatic approach?

The shale gas 'revolution' should be embraced as an opportunity rather than a threat, a Parliament Magazine roundtable was told. **Brian Johnson** reports.

**P**olish MEP Bogusław Sonik, speaking at the event organised by the Parliament Magazine in association with DMT and TÜV Nord, said that a more scientific debate on the issue was crucial in ensuring that Europe did not lose out on the potential economic benefits of unconventional gas exploitation. Sonik, who hosted the event, which focused on how policymakers could combine energy security and environmental safety within the unconventional gas debate, argued that misconceptions surrounding the health and environmental impact of unconventional gas extraction had primarily driven the European debate on the issue, rather than sound scientific evidence.

The Polish deputy's own initiative report on the potential negative impact of shale gas extraction – which was passed by a large majority of MEPs last November – emphasised that the extraction of unconventional gasses, such as shale gas, tight gas and coal bed methane, was environmentally safe and posed no health risks as long as strong environmental and safety standards were adhered to. "It's important," he added, "that MEPs lead the debate on issues such as energy and environmental safety. Our citizens have the right to expect that the European parliament will look carefully at this issue and take action to create legislation if required. But we must take into consideration what is happening across global energy markets, the US shale gas revolution must be taken into





account.” The US now produces around 15 per cent of its natural gas supplies from unconventional sources, which has helped to dramatically reduce domestic energy prices. Predictions suggest that production could be as high as 50 per cent by 2030.

However, the issue at the heart of the fierce debate over the safety of unconventional gas is the controversial extraction process of hydraulic fracturing, or fracking. Fracking involves drilling into gas filled rock formations then fracturing them with a high pressure mix of water, sand and chemicals to release the trapped gases. Opponents argue that it can cause minor earthquakes and contaminate underground water supplies. But, supporters counter that the process is safe, has been used for decades, and that because fracking is undertaken several thousand metres below water tables, there is little risk of gas leakage related contamination.

Greek MEP Niki Tzavela, who also drafted an own initiative report on the industrial aspects of shale gas alongside that of Sonik last November, acknowledged, during a speech to

those attending the event ,that there was a need to distinguish the “realities from the myths” over unconventional gas exploitation. “I want to be clear,” she said. “Unconventional sources are not necessarily the panacea to all our energy problems. But somewhere along the line, we have to become more objective about how we examine the debate on unconventional gas in Europe. Up until now, that debate has not been based on scientific data and market analysis of the benefits that unconventional gas can

*“We must take into consideration what is happening across global energy markets, The US shale gas revolution must be taken into account”*

*Boguslaw Sonik*





## UNCONVENTIONAL GAS



*“The extreme techniques used to access and extract unconventional gas reserves generate cumulative impacts at both local and global levels, on climate and on people’s health and environment”*

*Antoine Simon*

the early rush to explore and drill “without cleaning up the mess they left”. “However, I believe that since the two reports on unconventional sources were adopted by the European parliament last November, industries and companies have taken good note of this and have reacted positively. We have to be more pragmatic about the approach we take on energy policy. Promoting the deployment of more renewables and energy efficiency is all well and good. I fully support this. But we don’t have to be dogmatic. Just because we support renewables and energy efficiency measures doesn’t mean that we have to

have on industry and competitiveness. The debate has been about whether ‘Gaslands’ [a 2010 documentary on the alleged environmental and health impact of unconventional gas drilling and extraction on rural communities in the US] is real or not. So number one, we have to separate the realities from the myths.”

Tzavela acknowledged that the extractive industries had not helped their case in

exclude everything else. This would be completely unrealistic.”

Attendees also heard from Ralph Schlüter, deputy head of geology and borehole survey at engineering group DMT, who opened his presentation with an amended Time magazine cover image of a piece of shale rock with the headline, ‘This rock could power Europe’. While outlining the technical processes involved in fracking, Schlüter posed the question of whether additional rules on unconventional gas extraction were needed to enable a “golden age of gas” to develop in Europe. “If there is no public acceptance then Europe will never get to a position of industrial production of unconventional gas,” he stressed.

Andrea Strachinescu, head of unit for new energy technologies in the European commission’s energy directorate, argued that both energy security and environmental safety were equally important, saying that there can be no trade off between the two. Strachinescu said that the shale gas revolution in the US had led from a switch from coal to gas with a corresponding reduction in CO2 emissions, but at the moment “it was difficult to actually assess if we have similar shale gas [potential] in Europe”. She told participants that the commission was currently running a public consultation on shale gas. “But before any decisions will be taken, everything will have to be properly analysed. Shale gas could be an important part of the EU’s energy mix, but it must benefit citizens; there can be no trade-off.”

However, Antoine Simon from Friends of the Earth Europe questioned the overarching theme of the event, arguing that it “implicitly asks participants and decision makers to find a compromise between energy security and environmental safety”. Simon said that the impact of unconventional gas extraction was constantly downplayed by its proponents, yet questioned why then were environmental safety measures being debated so much if the extraction process was, as alleged, already safe and well-regulated. “The extreme techniques used to access and extract unconventional gas reserves generate cumulative impacts at both local and global levels, on climate and on people’s health and environment that can hardly be properly regulated and are far beyond what can be considered as a reasonable level of risk.” Simon said industry arguments that fracking technology was nothing new were misleading as modern hydraulic fracturing techniques were very different to processes used over the years to stimulate access to conventional gas reserves.

“The new technology has been developed to access a much more difficult kind of geology. The new type of drilling requires the use of many new chemicals, much more water, pumped at much higher pressure and therefore with much higher impacts, whether inherent or accidental, for surface and ground habitats.” Simon also criticised what he called the “one per



*“We have to be more pragmatic about the approach we take on energy policy”*

*Niki Tzavela*



*“Shale gas could be an important part of the EU’s energy mix, but it must benefit citizens; there can be no trade off”*  
*Andrea Strachinescu*

fracking process. “Proponents argue that chemicals represent only one per cent of fracking fluids. However, one per cent of a 20 million litre fluid represents several tonnes of chemicals for each fracking operation.”

Pro-unconventional gas deputies, Konrad Szymański and Roger Helmer were quick to respond to Simon’s comments, with the Polish ECR MEP making a passionate plea to learn from the mistakes of the US and move to develop unconventional gas activities. “I agree that there can be no trade off on environmental safety concerns. I don’t know anyone in this parliament that doesn’t want to follow strict environmental legislation. However, we have the chance to learn something and to avoid the mistakes made in North America”, said Szymański. British deputy Helmer argued that most of the objections used against developing Europe’s unconventional gas resources could be used for any type of energy-related drilling operations. “Those risks are there to be managed and regulated. Unconventional gas is a gift from heaven for Europe. It would be wholly irresponsible if we just turned our backs on it,” said Helmer.

cent myth” regarding the use of chemicals in the

Closing the debate, Guido Rettig CEO of technology service provider TÜV Nord said that it was clear that there could be a “very important economic impact if Europe could deliver unconventional gas”, and that the EU needed to show the way. Rettig said that any uptake on developing unconventional gas resources “depends on our innovation and our capability to reduce energy imports while enhancing production. However, on energy policy, it’s up to EU member states to decide, but the ball is now in the European commission’s court.” ★

*“On energy policy, it’s up to EU member states to decide, but the ball is now in the European commission’s court”*  
*Guido Rettig*



*“If there is no public acceptance then Europe will never get to a position of industrial production of unconventional gas”*  
*Ralph Schlüter*





# Leaving EU?

As creator of the single market and leader of defence and foreign policy Britain should be leading, not leaving, the EU, argues **Peter Wilder**

**T**oday's European Union is a canvas onto which a new vision of European cooperation can be painted. Federalising forces are alive, of course, and remain the stuff of eurosceptic nightmares. But equally the forces pressing to liberalise the EU in order to face a world of globalised market states working in economic blocs are just as strong. Unfortunately, the natural leader of this cause – the UK – is unable and unwilling to get out of first gear to make its case. For friends and allies witnessing this, it is a sad fate for a great country.

Why? The lion's roar now whimpers. When asked how much influence Britain has in Europe, up to 80 per cent of Brits polled think they have none. Britain suffers delusions of weakness not strength. With a media hell-bent on demonising Europe and politicians frightened of selling a vision, people feel dragged along in a relentless tide of negative fantasy in which Britain is a Gulliver tied down by EU Lilliputians.

Peter Wilding is director of the think tank British influence through Europe



*“When asked how much influence Britain has in Europe, up to 80 per cent of Brits polled think they have none”*

The opposite and positive reality: that Britain is free to shape Europe's future – in its role as creator of the single market and leader in defence and foreign policy – is not heard.

Few Brits would know that the two great achievements of the European project over the past 30 years – the single market and the push to the east – were largely driven by them. British diplomats are, along with the French, regarded as the most effective in Brussels. The determination to complete the single market has supporters in northern Europe, the accession countries and the European commission itself. But the gap between the British public's mood of resentful low self-esteem and the political reality is where euroscepticism has grown.

So Britain needs to stop whimpering and practice an active not passive approach. Last year, 18 EU prime ministers signed David Cameron's manifesto urging the completion of the single market. Together with the current prospect of the US-EU free trade agreement, the UK has a vital position in promoting competitiveness in order to boost European growth and create jobs.

Also, the rise of Russia into a fully-fledged energy state and the Islamic fundamentalist turbulence in the gas-rich deserts of north Africa requires Britain to lead European defence alliances and provide common purpose. The fact is that Britain is already working closely with France and other military allies in the EU.

But this positive reality is unheard in Britain. There, a nostalgic back-to-the-future message of a UK free of the yoke of supranational entanglements is enough. In the mayhem of political and economic instability that currently troubles the establishment, this vision is the hallucinatory drug pleasing the populace. British influence has been set up to challenge this historic error. The rationale for British influence in Europe today is stronger, not weaker, than it was 40 years ago. Then the rationale was prosperity. Today it is also about power in a world which is undergoing its biggest change in centuries. In this new world, to leverage power, Britain needs the heft of the EU. This is true in economics, in trade, in defence, foreign policy, the very issues where Britain should be leading – not leaving – the political scene. ★



# Defence matters

Policymakers, industrialists and the military are calling on EU leaders to prioritise Europe's defence needs in the face of budget cuts. **Rajnish Singh** reports

EU council president Herman Van Rompuy and EDA chief executive Claude-France Arnould

In her opening remarks at the European defence agency's (EDA) annual conference, chief executive Claude-France Arnould told delegates that EU defence ministers have already recognised the challenge of shrinking budgets. "When, in November 2011, defence ministers approved 11 'pooling and sharing' priorities, they sent a clear signal that in times of austerity, complex operations and highly advanced technology, acting together is essential if Europe is to preserve and develop the capabilities it requires."

The conference took place in Brussels last week titled "European defence matters". Over 500 people gathered, including diplomats, members of the EU institutions, think tanks, and defence industry and military leaders, to discuss how Europe can enhance its military capabilities in the face of increasing budget cuts. Dominating the comments from delegates and speakers was the upcoming EU council summit in December, in which defence and security issues will be under discussion. The general consensus in the conference was that EU leaders must take critical decisions on finance and enhancing the power of the EU institutions if they are to meet the current and future security challenges facing Europe.

EU foreign policy chief Catherine Ashton highlighted the fact that defence cuts had already come on top of two decades of post-cold war reductions. She cited cyber security and piracy, along with the increasing demands to act in regional conflicts such as Mali and Libya, as the new threats facing Europe. She said, "there is no reduction in the need for Europe to be able to act militarily. If anything, I would argue, it's increasing."

For Ashton there were three key reasons for more investment in security and defence. The first was the political aim of fulfilling

Europe's ambitions on the world stage. The second was the operational need to ensure that Europe had the right military capabilities to be able to act. And the third was the economic requirement of maintaining jobs, innovation and growth. However, she did not expect overall European defence budgets to suddenly increase, saying, "we have to do better with our existing resources and capabilities".

Though Ireland is not a member of Nato, Irish defence minister Alan Shatter pointed out his country's participation and support for the EDA, especially in relation to crisis management and international peace support operations. "I am of the opinion that European defence does indeed matter," he said.

"If current trends persist we risk losing 12 per cent of overall defence spending" – an equivalent to the entire current defence budgets of Poland, Spain and the Netherlands – "since the start of the economic crisis," warned EU council president Herman Van Rompuy. For Van Rompuy, it was not a question of how much money was spent on defence, but how it was spent. He went on to highlight that, as a whole, the EU had more troops than the US, but the capacity to deploy these troops was more limited. "The fact is that vast amounts of money still go on maintaining costly, obsolete equipment at the expense of essential investments," stressed the former Belgian prime minister.

*"If current trends persist we risk losing 12 per cent of overall defence spending since the start of the economic crisis"*

*Herman Van Rompuy*

Echoing many of the views of the military industrialists attending the conference, global defence corporation EADS chief executive Tom Enders warned that if budgets are not increased, Europe could lose key skilled personnel to civil industry, having an impact on future military research and innovation. Arnould concluded the conference by issuing a call to participants, as well as EU heads of state, to "close the gap between rhetoric and reality". ★

## Regional leaders call for 'flexibility' on new 'green shipping' rules

Leaders from Europe's regions have called for "more flexibility" in implementing new EU rules on "green shipping". They say the timescale for introducing "drastic" reductions in sulphur emissions from ships is too short.

A conference heard that the new rules, contained in a directive adopted last year, will require "considerable" investment from both port authorities and ship owners. Delegates supported the directive's environmental aims in seeking to achieve "greener" shipping. A final declaration said they "wanted to contribute to a better implementation of these provisions in supporting ship owners and stakeholders in their adaptation efforts".

However, the adjustment period envisaged by the direc-



tive was deemed to be "very short" by the conference organiser, the conference of maritime and peripheral regions. The organisation is now urging member states, the commission and the international maritime organisation to show "flexibility" in the implementation of the directive.

Wulfran Despicht, a representative from Calais, said, "The implementation of this directive may generate economic and industrial opportunities for the regions. Yet I wonder if the various economic players have been made sufficiently aware of the issues relating to the implementation of the directive and, above all, if the investment can be funded after 2015 and by whom."

## NGOs call for more awareness of 'failing' EU flagship policy

The European citizens' initiative (ECI), an EU flagship policy, has been accused of falling "well short" of expectations. The condemnation came as the ECI initiative geared up to mark its first anniversary on 1 April. It was launched 12 months ago in a blaze of publicity by EU commissioner Maroš Šefcovic who described it as one of the EU's flagship policies.

However, a report by the European citizen action service and democracy international concludes, "For civil society organisations the date is not a reason to celebrate." The two groups say the initiative is "still too weak for real change". "One year after, the tool which was supposed to give more power to EU citizens is found to be the source of many problems." It says the initiative, which gives the right to citizens to demand the European commission legislates in a specific field, is "not sufficiently well known". "Urgent action is needed to raise awareness of the tool to bring ECIs to citizens and citizens to ECIs, to create a supportive infrastructure for organisers and to make the ECI more user-friendly and efficient."

The ECI requires one million signatures from at least seven EU member states in order to be submitted to the commission, from which the signatures must be distributed proportionately according to the size of the seven countries.



## Commissioner launches consultation on media freedom

European digital agenda commissioner Neelie Kroes has launched two consultations on media freedom and pluralism following a recommendation from the commission's high level group.

Kroes said, "We know Europe is a home of democracy, transparency and fundamental rights; we know that a free and pluralistic media is an essential part of that. But that does not mean there are no problems: whether of media concentration and lack of diversity, of restrictions on online and offline media or of state control, pressure and interference."

She said that Hungary was a "high-profile case", which remains unresolved, but the media issues are "not limited to one member state" and that there are "concerns and intense debates" across the EU.

Kroes added, "So today I announce the launch of two consultations on the recommendations of the high level group, starting today for 12 weeks and you are asked to give input." The first looks at national regulatory authorities who oversee audiovisual services under existing EU rules, and how to revise the EU law that applies to them, to both "strengthen" and "better guarantee their independence from governments". The second asks for views on each of the other recommendations of the high level group. Kroes said, "I call on all governments in the EU to take this debate seriously."



## Olaf refuses to comment on calls for its director general to quit

Olaf, the EU's anti-fraud agency has refused to be drawn on demands for the resignation of its director general Giovanni Kessler. The demand for the Italian to quit comes amid ongoing questions about Olaf's investigation into the circumstances surrounding the resignation of ex-EU health and consumer policy commissioner John Dalli.

It has been claimed that a representative for Swedish Match, the tobacco products company at the centre of the Olaf investigation, told French Greens MEP José Bové they were asked by the agency to lie when addressing a parliamentary committee on the Dalli case. Bové claims that Olaf instructed Swedish Match to "stick to their original version of events" when a company representative recently addressed the committee on budgetary control "even though they knew this version of events was no longer true".

This was a reference to a meeting said to have taken place between Dalli and Swedish Match, a manufacturer of snus, an oral tobacco.

Bové also said that an investigation by the Olaf supervisory committee, which oversees the agency's work, has shown that Olaf recorded conversations with witnesses without their knowledge – something the agency is not permitted to do – and that Kessler was aware of this.



## From the Twittersphere

**@SKMLatest** Silvana Koch-Mehrin MEP

@VivianeRedingEU ' #EP should decide on #quota proposal before the June council to give strong message to #EU member states' #womenboards



**@MartinSchulz** European parliament president Martin Schulz

A unanimous compromise in the European Council based on the lowest common denominator is not enough to secure the adoption of the #MFF #euco



**@VivianeRedingEU** European justice commissioner Viviane Reding

The European Parliament has called for action to get more women into boardrooms. The time to act is now. #EU #EP #womenboards



**@karsenis** Kriton Arsenis MEP

The world's #oceans are facing a bleak future, unless we rebuild its abundance, variety and vitality #overfishing



**@VassiliouEU** Education, culture, multilingualism and youth commissioner Androulla Vassiliou

I believe Greek/French film director Costas Gavras may be inspired for a new film based on the Cyprus saga of the crisis.



**@VerhofstadtGuy** ALDE leader Guy Verhofstadt

3 crises, #Cyprus #Hungary #Syria. #EU is failing in euro policy, failure of foreign policy, failing to uphold our democratic principles.



**@DanHannanMEP** Daniel Hannan MEP

Cyprus has made its choice. It could have bounced back and become Iceland. Instead, it will keep the euro and become Greece.



**@AlynSmithMEP** Alyn Smith MEP

Perhaps serious journalists having time in their busy days to be outraged at twitter is itself a symptom of why we're all in trouble.



**@SharonBowlesMEP** Sharon Bowles is chair of parliament's economic and monetary affairs committee

€100k+ depositor bail-in 'normal' for an individual bank resolution. Question is should it apply when fault not of individual bank's making?



**@ER\_Korhola** Eija-Riitta Korhola MEP

When MEPs report on a draft directive, it's like being a bra: we must support it, improve its shape and point it in the right direction.



## Report says 'deficiencies' persist in treatment of migrants at EU borders

A new report calls for an EU-wide ban on the return of migrants to third countries if this could put them in danger of 'inhuman or degrading' treatment. The report, by the EU's fundamental rights agency (FRA), also says policymakers should do more to increase fundamental rights protection of migrants when they arrive in the EU.



It says there have been "considerable" changes in the patterns of migration by sea over the last 10 years with arrivals rising "significantly" in 2011 following the Arab spring, before dropping again in 2012. FRA director Morten Kjaerum, said, "The EU and its member states must ensure that border surveillance and management, while necessary, are not detrimental to the fundamental rights of migrants arriving at our

shores. There are many reasons for people to venture the journey to Europe. Some are making use of their fundamental right to seek refuge from persecution in their home countries; some are looking for a better life for themselves and their families. But whatever the context of their arrival, we expect migrants entering the EU to be

afforded the same rights and treated with the same dignity accorded to any other person."

The report presents the results of in-depth research in four member states with southern EU sea borders. It describes the "hazardous" journey and deaths at sea, maritime surveillance mechanisms and the treatment of migrants when they arrive on shore.



# The International Law of Offshore Installations: Cutting Through Fragmented Regimes Towards Better Governance

## OFFSHORELAW

FP7-PEOPLE-2011-IEF Project 299703 (2012-2014)



**Seline Trevisanut** is Marie Curie Fellow at the Netherlands Institute for the Law of the Sea (NILOS) and Assistant Professor at the Law Department of the University of Utrecht.

Her fields of expertise are: public international law, law of the sea, international environmental law, EU law (maritime affairs, environmental policy).

She will further expend her expertise in energy law and EU energy policy.

Offshore installations rise in numbers and importance and promise high economic and scientific benefits, but they also increase risks of accidents and environmental damage. They offer profits, promise gains, and sometimes they bring about disasters. The Deepwater Horizon incident in the Gulf of Mexico has dramatically highlighted the gaps and weaknesses of the existing international legal framework concerning how to prevent, deal with and mitigate the consequences of similar environmental disasters. It has also poignantly illustrated the limits of the legal framework, which is fragmented along the lines of different geographical areas, different sectors of activities and, notably, different fields of law.

The OFFSHORELAW Project aims at spelling out the normative framework for offshore installations. From the fragmented and dissected legal material that does exist, it will carve out an 'international law of offshore installations'. No international treaty specifically regulates the issue as such. There is a plethora of instruments and of related bureaucracies, which deal with different aspects of installations' life, and which elaborate regulations in complete isolation one from the other. The lack of communication among the different frameworks generates conflicts and incoherencies between institutions and norms.

The on-going attempts of creating a specific legal framework follow a sectorial approach focusing on a specific economic field, either hydrocarbon industry or renewable energy.

They are useful in order to identify the problems that specifically concern these activities, but they do add to the legal fragmentation and stratification. The OFFSHORELAW Project does not oppose the adoption of new instruments, but supports a global approach in regulating the field at hand in order to avoid inconsistencies and solve the existing ones. This global approach does not necessarily entail the adoption of a new global instrument, but affirms the need of enhancing global cooperation and of eventually creating a global institutional framework.

The immediate gain from such a work is a contribution towards better ocean governance. Overall, the OFFSHORELAW Project strives to contribute to the preservation of the marine environment and the sustainable use of the oceans, while protecting the rights of the parties involved. More specifically and with a pragmatic twist, it then endeavours to provide useful legal tools to both private investors and policy makers



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# Licensed to drill

Member states must ensure the highest safety, health and environmental standards when it comes to offshore oil and gas, writes **Günther Oettinger**

**A**lmost three years ago, when the Macondo oil well blew up at the Deepwater Horizon drilling rig in the Gulf of Mexico, 11 lives were lost, and four million barrels of oil flowed into the ocean. This resulted in enormous damage to the environment and affected the livelihood of thousands of people in coastal communities. The world was shocked by the scope of the accident itself and even more so by how long it took to get things back under control. It seriously undermined public confidence in the offshore oil and gas industry, including in Europe. And we have to wonder what would happen in the event of a similar accident in EU waters.

Offshore energy production is vital for Europe's security of supply and competitiveness. Over 90 per cent of oil and 60 per cent of gas produced in the EU is extracted from beneath the seabed, and there are nearly 1000 oil and gas installations operating in European waters. In some areas like the North Sea, offshore drilling operates under a world-class safety regime, yet in other regions the rules are less developed. There is clearly room for improvement.

It is true that only 13 member states have ongoing offshore

operations, but we know that accidents do not stop at national borders. If a major accident took place anywhere in Europe, the damage caused by an oil spill would probably not be limited to the country where it occurred. Safety concerns all European citizens. This is why the commission reviewed the existing member states' safety frameworks for offshore operations, and proposed new legislation to guarantee that the world's highest safety, health and environmental standards apply everywhere in the EU. In February this year, the European parliament and the council reached a political agreement on the commission's legislative proposal on the safety of oil and gas operations in the EU. Once the European parliament and council formally approve the legislation, member states have to transpose it into national law and it will be applicable in the whole of the European Union.

This new framework is certainly not a rigid checklist of technical requirements, which may become outdated as the technology evolves or as offshore exploration and drilling moves into more challenging geological areas. Instead, the proposal focuses on safety criteria to be met by the industry and controlled by independent national experts.



Offshore energy production is a very complex and risky business. Oil wells and drilling rigs are like high-tech factories on ships that have to operate far offshore in cold water, often in depths of over 1000 metres. The water pressure is such that maintenance and, if necessary, rescue work, has to be done by remote control. This should not be used as an excuse. We must ensure that member states only authorise companies with sufficient technical expertise and financial capacity to work in EU waters.

According to new standards, offshore companies will have to prepare a risk assessment and an emergency response plan before activities can begin. These plans and their future alteration will have to be checked by independent experts and get a green light from national authorities. Moreover, inspectors will also regularly visit the oil platforms and do on-the-spot checks that all safety rules are being rigorously followed. If this is not the case, a company may be required to stop drilling immediately. The results of these inspections will be made available to the public, so that citizens can see whether safety standards are properly applied.

In addition to prevention, the new directive will ensure that we react wisely and promptly in the event of an accident. The company working at the well must have equipment on site that can be put immediately into operation.

We also have to make sure that the environment and the livelihood of local communities are not put at risk if the operator is no longer able to control the accident. In such cases, national emergency resources must be at the ready to intervene. And the resources and expertise of neighbouring member states, as well as the European maritime safety agency, will also be available to help limit the damage if an accident overwhelms national capacity. To be even more effective the European commission proposes to extend the environmental liability from 22 km to 370 km off the coasts of member states, thus covering all installations.

Last, but not least, it is in our best interests that

offshore safety is pursued in neighbouring countries and beyond. Therefore the commission will work with its international partners to promote the implementation of the highest global safety standards. EU companies should then be expected to apply EU safety standards whenever they work overseas.

All these measures seem to be common sense and do not prevent member states from applying even stricter rules, but it is our duty to guarantee that every operator within the EU maintains this high level of safety. National authorities remain the best placed to control this, but we must ensure that these rules are applicable everywhere in the same way. This is good for operators already applying high standards. And it is what EU citizens have the right to expect. ★



*"If a major accident took place anywhere in Europe, the damage caused by an oil spill would probably not be limited to the country where it occurred"*

Günther Oettinger  
is European energy  
commissioner



# Risk prevention

Safety is central to the EU's new offshore oil and gas proposals, for both citizens and the environment, writes **Pat Rabbitte**

**O**n 13 October 2010, the European commission presented a communication called 'Facing the challenge of the safety of offshore oil and gas operations'. Following the disaster in the Gulf of Mexico in April 2010, the commission carried out an analysis of the legislative and regulatory situation in the European Union, and suggested a course of action, including revision of existing legislation, as well as future new proposals, strengthening EU intervention capacity, and action at regional and global levels.

Following detailed negotiations among member states, agreement has now been reached on a proposal on safety of offshore oil and gas prospecting, exploration and production activities. The offshore safety directive provides for a new area of competence for the EU in the respect of the regulation of offshore oil and gas exploration and production activities addressing their potential to give rise to both safety and major environmental hazards. From an EU council perspective the directive introduces a number of very important and complex provisions for improving safety for offshore gas and oil drilling which include, in the first instance, reaching agreement on a text relating to the establishment of the competent authority in each member state. The position agreed recognises both the difference in activity levels among member states and the potential additional burden on them, which the new directive could give rise to. While the agreement achieved acknowledges the need to have regard to such factors, it does so without diluting the need for safety at all times.

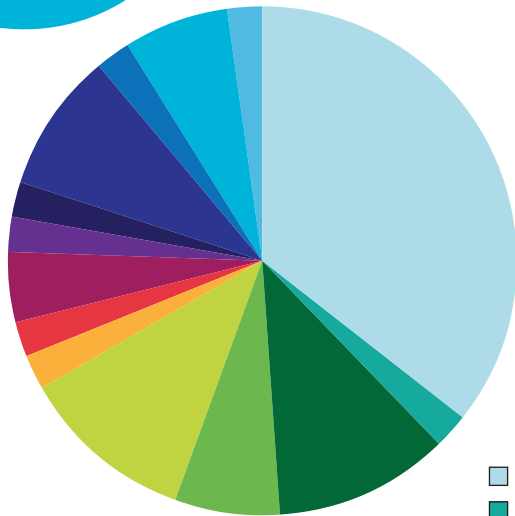
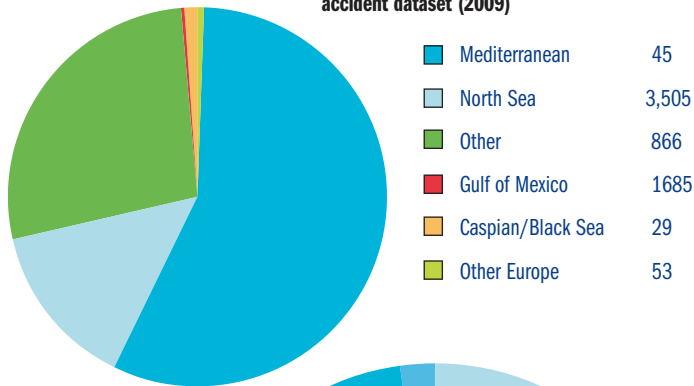
The issue of liability regimes is also addressed, and it was the view of the council that it could not come to a pre-judgment on such a crucial issue pending the outcome of EU commission studies, which are due to report next year. Another matter of considerable significance is the inclusion of provisions with regard to public participation, ensuring that either the strategic environmental assessment or environmental impact assessment would be undertaken with respect to all relevant offshore activities prior to their approval and commencement. Other noteworthy issues that are included are confidential reporting, response effectiveness, activities in the Arctic, the role of the European maritime safety agency, activities outside the →



*"Ultimately our goal as policymakers in the area of offshore exploration activity is to improve safety in extremely challenging environments"*



**Geographical location of all recorded offshore oil and gas drilling accidents according to world offshore accident dataset (2009)**



**Offshore oil and gas drilling accidents in the Mediterranean between 1970 and 2009 (WOAD)**

Italy	16	Egypt	5	Turkey	1	Malta	3
Israel	1	Cyprus	1	Tunisia	1	Libya	1
Greece	5	Algeria	1	Spain	4		
France	3	Yugoslavia	2	Morocco	1		

EU and criminalising conduct leading to a major accident.

The agreement reached will ensure a consistent use of best practices for major hazards control by oil and gas industry offshore operations potentially affecting Union waters or shores, implement best regulatory practices in all European jurisdictions with offshore oil and gas activities, strengthen the Union's preparedness and response capacity to deal with emergencies potentially affecting EU citizens or the environment, and improve and clarify existing liability and compensation provisions. Ultimately our goal as policy-makers in the area of offshore exploration activity is to improve safety in extremely challenging environments. There will be significant safety measures arising from this directive that will benefit our global environment. ★

**Offshore hydrocarbon drilling in Europe**

- Nearly 1000 offshore installations are operating in the EU
- The European commission estimates the annual costs of offshore oil and gas accidents in the EU to be in the range of €205m-€915m.
- Between 1974 and 2010, 2.2 million tonnes of oil were spilled during exploration and production activities.
- The Deepwater Horizon disaster has so far cost BP €28.3bn.
- There is no international treaty requiring compensation to be provided in cases of spills from offshore installations. Currently, only maritime accidents are covered in the international oil pollution compensation funds of 1992.

Source: Oceana

Pat Rabbitte is Ireland's communications, energy and natural resources minister

Source: World offshore accident dataset 2009





*“Companies operating in EU waters must demonstrate that their risk prevention policy also applies to operations outside the EU”*

# After Deepwater Horizon

New rules for offshore oil and gas drilling developed in the wake of the 2010 Gulf of Mexico oil spill will improve the EU's ability to cope with future emergencies, says **Ivo Belet**

**T**he mechanics of European policy often function too slowly. But the commission acted quickly after the Deepwater Horizon drama in the Gulf of Mexico, launching a thorough overhaul of the existing safety legislation for drilling operations. If a similar accident were to happen in EU waters this could have serious consequences across member states' borders. Recognising the need to make drilling operations at sea safer, the European parliament endorsed a profound adaptation of the existing legal framework.

The proposal that the European commission presented on the safety of offshore oil and gas prospecting, exploration and production activities, was aimed primarily and rightly at reducing the risk of major accidents to limit their consequences for the environment and for people. This objective is of course supported by the European parliament. Given the different environmental, health and safety approaches in the member states, aligning these is key to safety. The proposal therefore aims at applying recognised global best practice in major hazard management throughout the EU. Adequate emergency response

is vital to limit the consequences of any spill or accident. Therefore, the new legal framework will thoroughly improve the EU's preparedness and response capacity to deal with emergencies, including the liability and compensation provisions.

While agreeing with the overall objectives of the commission's proposal, the European parliament's major concern is the independence of the authority supervising the safety and environmental risks of operations. The accident on the Deepwater Horizon rig demonstrates just how crucial a truly independent supervisory body is. As Bob Graham, co-chair of the US oil spill commission, says, “Only a truly independent federal safety agency – totally separated from leasing practices and politics – can provide certainty that the regulators do not again become captive to the industry.”

Not all EU member states were enthusiastic about such a structural separation sought for by the parliament. Instead, some advocated that a functional separation would be sufficient to avoid conflicts of interests. Nevertheless, the European parliament has succeeded in having accepted the structural separation as a general principle. However, for member states that have





*“Adequate emergency response is vital to limit the consequences of any spill or accident”*

**An oil slick is seen as the Deepwater Horizon oil rig burns in April 2010**

### Offshore installations

There are nearly 1000 offshore installations operating in the EU, distributed among member states as follows:

UK: 486; Netherlands: 181; Italy: 123; Denmark: 61; Romania: 7; Spain: 4; Poland: 3; Germany: 2; Ireland: 2; Greece: 2; Bulgaria: 1.

Drilling operations have recently started in Cyprus. In Malta, offshore licences have been awarded, but currently there are no offshore activities yet.

less than six offshore installations, a functional separation is allowed, provided it

is monitored appropriately (see textbox for details of offshore installations across member states).

The environmental damage caused by oil spills is, in most cases, considerable and the costs of cleaning up are high. The European parliament has managed to clarify the rules governing the licensing process. Strict conditions are imposed to companies applying for a licence, demanding them to provide, before the start of the operations, evidence of their financial ability to cover the liability for potential environmental and economic damage.

The new regulation also addresses operations worldwide. Companies operating in EU waters must demonstrate that their risk prevention policy also applies to operations outside the EU. The European parliament made it compulsory for companies registered in the EU to report on accidents that occur outside the EU. Also, whistle blowing procedures set up for confidential reporting of safety and environmental concerns apply to people involved in operations in third countries.

Since the EU has no waters in the Arctic, except for autonomous Greenland, it does not make much sense to call for a moratorium on drilling in this area. Therefore, it has been

agreed that within the Arctic council the highest safety standards for oil drilling must be promoted. The effectiveness of the emergency response must also be assessed in all weather conditions. This is a crucial condition for all companies that consider applying for an exploration licence in a remote and sensitive area such as the Arctic.

On the role of the European maritime safety agency (Emsa), parliament has managed to secure its added value with regard to emergency planning. All new tasks conferred to Emsa have been decided in accordance with the agency's capacities, budget and legal framework. Several colleagues and stakeholders were in favour of an even stronger role for Emsa, allowing it to check compliance and enforcement of the new legislation. While theoretically a perfect proposal, in practice, without extra resources, this enlarged mandate would be an empty shell.

Public consultation for projects with environmental impact is foreseen in the environmental legislation (environmental impact assessment). However, some member states have implemented the EU rules in such a way that that some offshore oil and gas projects would escape this assessment. The agreement between parliament and council guarantees that, also in those cases, an early and efficient public participation is undertaken before the commencement of any operations. The trilogue agreement has been largely supported in parliament's energy committee and is now ready for the plenary vote scheduled in May. ★

Ivo Belet is parliament's rapporteur on the draft directive for offshore oil and gas



# Risk Screening – Horizon 2020: From iNTeg-Risk to the E2R2 – European Emerging Risk Radar



iNTeg-Risk-STOA workshop – European Emerging Risk Radar (E2R2) Initiative: “Matching the technology challenges of 2020”

**iNTeg-Risk** is a large-scale project funded by the European Union’s Seventh Framework Programme (EU-FP7/2007-2013) under grant agreement n° 213345. It aims at improving the management of emerging risks related to new technologies in the European industry, as well as promoting safety, security, environmental friendliness and social responsibility as a competitive advantage and trademark of the EU technologies. The project involves renowned R&D institutions as well as leading EU industries and it is coordinated by the European Virtual Institute for Integrated Risk Management (EU-VRI), a company founded with the goal to ensure exploitation and sustainability of the iNTeg-Risk results after the project ends in May 2013. Therefore, the European Emerging Risk Radar (E2R2) Initiative is envisioned as one of the potential ways to achieve this goal and it will leverage on the iNTeg-Risk results as its baseline (see <http://www.eu-vri.eu/fwlink/?LinkID=431>).

The E2R2 Initiative aims to provide policy makers and the industry a scientifically robust and independent mechanism for an adequate assessment of emerging risks, hence it is envisaged as a platform which enables early recognition, better monitoring and integrated management of emerging risks at the European level – a modern, web-based “system-of-systems”, processing inputs from different sources (e.g. scientific data, social

media, expert opinions, etc.) and delivering user-tailored outputs to specific users’ groups. These outputs will contain, for instance:

- customizable “radar-like” visualization of emerging risks,
- relationships among emerging risks in GIS and conceptual-maps,
- validation of risks and comparison of different views on risks,
- possibility of identification and analysis (forecasting) of trends,
- possibility to drill-down on single points,
- possibility to create reports on specific topics, ranging from “two pager” to “topical reports”.

A vision as such therefore led EU-VRI and the iNTeg-Risk Consortium to prepare the Science and Technology Options Assessment (STOA) workshop together with the STOA Committee of the European Parliament, where the E2R2 Initiative is proposed as a tangible showcase for innovation and Public-Private-Partnership (PPP). The workshop took place in November 2012 at the European Parliament in Brussels and was proven a great success with very positive support from the industry, academia as well as the public sector. Results



Innovative risk monitoring tool, RiskRadar, developed within the iNTeg-Risk project

of this workshop are accessible on the iNTeg-Risk website (<http://www.eu-vri.eu/fwlink/?LinkID=432>) and the STOA web page (<http://www.europarl.europa.eu/stoa/cms/home/events/workshops/integ>) dedicated to this event. In addition, a special news release of the workshop can also be accessed at <http://www.eu-vri.eu/fwlink/?LinkID=433>.



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# Best practice

Europe must continue to look at better ways to improve its approach to offshore oil safety, argues **Vicky Ford**

Vicky Ford is parliament's rapporteur on facing the challenge of the safety of offshore oil and gas activities' and ECR shadow rapporteur on safety of offshore oil and gas prospection, exploration and production activities

Following the tragic events in the Gulf of Mexico in 2010, it was right that the EU looked at its approach to the offshore sector – after European energy commissioner Günther Oettinger revised his initial calls for an EU wide moratorium on offshore drilling in the wake of the disaster.

Being from the UK, where we have more offshore oil than the rest of the EU put together, I was naturally concerned at the introduction of new EU legislation in this area given how it could affect the UK both environmentally and economically. The UK takes a site-specific approach to safety, it is not the tick-box culture which was identified as a major contributing factor to the Gulf of Mexico disaster.

The biggest talking point regarding the commission's proposals was their decision to propose the legislation as a regulation, not a directive. While many of the proposals were based on North Sea practices, which have been held up as a world-class example of safety, a regulation would have forced

EU member states, and in particular the UK, to repeal huge parts of their legal frameworks and insert the new legislation in its place. Not only would we have been walking into a legal nightmare in an industry where we have seen that the results of bad legislation can be catastrophic, but it would also mean that the finite number of safety experts that

exist would have been office-bound for months, if not years, transposing the new legislation instead of being on-site inspecting the safety of installations. Ultimately it was particularly pleasing that both parliament's environment and industry committees voted in favour of changing the proposals to a directive, meaning that negotiations with the council, who had already opted to change the legal base, could focus on the more substantive and detailed aspects of the proposals.

It is right that there is an enhanced role for European maritime safety agency (EMSA) in areas where they can genuinely add value, such as cataloguing all available emergency response equipment throughout the EU and also using their CleanSeaNet service to monitor any pollution originating from offshore platforms. However, it was extremely alarming that certain areas of parliament were calling for EMSA to become an "EU super regulator" for the offshore sector, despite the agency having no experience or resources in this field and importantly no desire to actually fulfil these functions given its primary role focuses on the shipping sector. This type of centralisation would have missed the point and gone against the lessons from the Gulf of Mexico tragedy – we need local experts familiar with local conditions.

There are still difficult questions to answer in terms of liability and we look forward to the results of the commission's continued work in this area. The 'polluter pays' principle is enshrined in the EU treaties and proposals to improve and clarify Union liability and compensation provisions would be welcomed. Parliament also successfully inserted a requirement for EU headquartered companies to apply their corporate major accident prevention policy to installations outside the EU. I hope this brings the intended tangible results and that it doesn't, as I fear, become another legal requirement that oil majors can wriggle out of leading this clause to deliver on paper but not in practice.

The most important lesson we can learn is that we should never be complacent and must always be looking for ways to further improve and perfect our approaches to offshore safety. ★



*"There are still difficult questions to answer in terms of liability and we look forward to the results of the commission's continued work in this area"*



# Game changer?

New clinical trials legislation will aid economic recovery while encouraging pharmaceutical innovation and healthcare investment, writes **Paola Testori Coggi**

Last summer, the European commission tabled a proposal to revise the current legislation on clinical trials. The proposed regulation will repeal the 2001 clinical trials directive which has been heavily criticised for the excessive red tape, high administrative costs and long authorisation delays it has brought about. The commission recognises that the original directive has been, to a large extent, responsible for a significant drop in clinical trials applications in recent years. The figures show a 25 per cent drop in applications for clinical trials in the EU between 2007 and 2011. This is not surprising, as the data also show the related administrative costs went up by 98 per cent and the average delay for launching a clinical trial up by 90 per cent to 152 days.

One aspect of the 2001 directive that has withstood criticism is the level of protection it ensures to trial volunteers. With the new clinical trials proposal we have endeavoured to rectify the shortcomings of the previous legal framework while maintaining the high standards of patient safety. I am confident that the new regulation, once in force, will be a game changer for clinical research in the EU. It will serve as an incentive for clinicians and researchers to apply for and conduct clinical trials in Europe, encourage more multi-national trials – essential, for example, for research on rare diseases, and ultimately resulting in new and more innovative medicines on the EU market.

Before I outline some of the features I find the most interesting in this proposal, let me explain what clinical trials are and why we need them in Europe.

Clinical trials are a means of testing the safety and effectiveness of new medicines or new indications for existing medicines on human volunteers. They are thus a vital step in the development of new and safe medicines and in the improvement of existing treatments. They are crucial for patients affected by serious or rare diseases – as they are the only way for them to have access to the most advanced, life-saving treatments. A recent, long-term study published in the Oxford annals of oncology supports this, with

its clear conclusion that access to clinical trials drives dramatic increases in survival from childhood cancer.

Conducting clinical trials in Europe is also good for economic recovery, as clinical research is an important step in pharmaceutical innovation and investment in healthcare. This is a booming sector in the EU, with over €20bn being spent



*"I am confident that the new regulation, once in force, will be a game changer for clinical research in the EU"*



every-year on healthcare-related research and development.

So how will this proposal bring about positive changes? First off, the legal act will now be a regulation which gives less leeway for interpretation and should result in uniform implementation by member states. Simplification of current rules include a 'one-stop' database for submitting applications, a flexible and quick assessment procedure, a simplified reporting system and clearer, simpler rules for running multi-national trials. The proposal also introduces procedures balanced to the risks for trial volunteers, for example comparing two already authorised medicines is, in principle, less risky than a trial with a new drug, while upholding the highest safety standards. Possibilities for enforcement are also factored in to the proposal as it will allow the commission to conduct controls in the EU and beyond.

Other interesting features are the introduction of the concept of 'co-sponsorship' with the clarification that in cases where a clinical trial is conducted by more than one sponsor - they are able to split the responsibility between them, and new

rules on compensation for damages. On this second issue, the proposed regulation acknowledges that clinical trials are not always riskier than treatment in normal clinical practice and makes a distinction in indemnity rules between trials that do and that do not pose additional risks for the human subjects.

Many people agree that these new rules make sense. Since its adoption, the proposal has been presented to and discussed by a broad range of stakeholders. It has received enthusiastic support from non-commercial and commercial organisations alike, who have openly stated that the proposed regulation "will give clinicians and researchers a better framework for developing and testing treatments, to benefit patients across Europe, while maintaining the high standards of patient safety that currently exist in European clinical research". The proposal is now being discussed in the council and parliament and we are confident that the discussions between the co-legislators will go smoothly and the proposal adopted quickly. The sooner the regulation is adopted, the faster it will help further enhance the health of patients and clinical research in Europe. ★

Paola Testori Coggi  
is director general  
of the European  
commission's  
DG health and  
consumers



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# Trial and error

The EU's revised clinical trials directive must reduce bureaucracy while guaranteeing the highest levels of protection, argues **Peter Liese**

Peter Liese is parliament's EPP group health spokesperson

**W**e still cannot treat most life-threatening and debilitating diseases and even when we can treat them we must, however, accept certain side effects. That is why research in new pharmaceuticals is as urgent as ever. After experiments with computer models, cell cultures, and animal testing, one has to test the new drugs on human beings. That is why clinical trials are an unavoidable and necessary step in this development.

On July 17 2012, the European commission presented a proposal for a regulation on clinical trials. The proposal is

supposed to initiate the process of simplification and harmonisation of clinical trials all over Europe and replace the directive from 2001. This directive has brought many benefits and improved the protection of patients, but it also has critical vulnerabilities.

In general, I welcome the proposal of the European commission to make multinational clinical trials less bureaucratic. Not

only will the pharmaceutical industry benefit, but, in particular, independent researchers will also gain from the directive, providing better services to patients all over Europe. Low risk clinical trials, for example, are mainly conducted by non-commercial sponsors like NGOs, scientific organisations and charities. They normally use existing drugs. Sponsors of non-commercial clinical trials suffer severely from the burden of the current directive. That is why simplification is needed. However, the protection of patients within this process should not be reduced

An established and internationally recognised standard practice of protecting the research involving human subjects is the use of an independent, interdisciplinary ethics committee which needs to consider, comment on, and approve research projects. The proposal does not contain such explicit requirements and refers to a self-dependent organisation of each member state. I am convinced that this must be changed to ensure patient protection. The role of the ethics committee is especially important because the regulation will set a standard for third countries. Many clinical trials that lead to market approval in Europe are done in third countries like India or African countries. If we do not explicitly mention ethics committees how can we demand their use in third countries?

A further weakness of the proposal is that the protection of children and mentally disabled persons – people who are not able to give informed consent – has been weakened compared to the current directive. This is unacceptable and would undermine the credibility of the proposal. That is why I believe the text of the current directive needs to be re-examined.

The third issue that has to be improved is the relationship between the reporting member states that performs a risk benefit assessment for clinical trials and other concerned member states. I think the role of the other concerned member states needs to be strengthened to guarantee the highest possible safety standards. The debate in parliament's environment, public health and food safety committee – which is responsible for this dossier – has shown a lot of progress. In the current form, the text is not acceptable, but I am optimistic that in the end it will bring about the necessary simplification while simultaneously guaranteeing the highest possible protection standards. ★

*"Sponsors of non-commercial clinical trials suffer severely from the burden of the current directive"*

# Testing times

The full results of all clinical trials carried out in the EU must be published if Europe is to remain an attractive place for medical research, argues **Glenis Willmott**

Everybody agrees that the legislation on clinical trials must change. Many have criticised the current clinical trials directive, saying it is partially to blame for the drop in clinical trials over recent years. Between 2007 and 2011, the number of clinical trials in Europe dropped by 25 per cent.

Of course that is not to say that we do not need European legislation on clinical trials. Without harmonised rules across the EU it is very difficult to conduct cross-border trials. And EU legislation has set minimum standards for patient safety across Europe. Unfortunately many requirements were made with large pharmaceutical companies in mind, overlooking those trials carried out by non-commercial sponsors. Most importantly the directive was implemented differently across the EU, resulting in a patchwork of laws, which are extremely difficult for researchers to navigate. Cross-border trials needed to be authorised in each member state, each using slightly different rules. Research into rare diseases is suffering, which, due to small patient populations, has to be done in a number of countries. For these trials the administrative costs can be prohibitive.

The commission's proposal for a clinical trials regulation has generally been welcomed by stakeholders. The fact that the legislation will be a regulation rather than a directive will leave no room for differences in implementation. An even bigger step will be the single EU portal, where all clinical trial applications will be sent, regardless of where in the EU they are conducted, and in how many member states. National authorities will work together on the scientific assessment of multistate trials, with one member state taking the lead. These assessments should be completed within strict timelines. Simplifying trial applications in this way will once again make Europe an attractive and competitive place for medical research.

We must also take a more risk-based approach to trials. At the moment a medical research charity looking at the effects of vitamin D and a pharmaceutical company testing a new experimental drug

must fulfil similar requirements. To deal with this the new definition of 'low intervention' trials will be introduced. If a trial uses a well-known drug and doesn't include any risky interventions, the researchers will have fewer obligations and less paperwork to fill out, and the trials will be authorised faster. →



*"A new EU database will be set up to record all trials carried out in the EU, which will be a fantastic step forward"*



## CLINICAL TRIALS

A more controversial issue will be the idea of national indemnification systems. Since the directive came into force some clinical trial insurance costs have risen by 800 per cent. The fees greatly outweigh the claims. Some member states, such as Denmark, already have indemnity schemes in place. This means the state can insure the trial. I want these schemes to be available in every EU country, free of charge for academic sponsors. I know it will be difficult to convince governments to agree to this. However, when you consider that public money on medical research is being spent on extremely expensive insurance cover, it makes sense.

All of these measures should make the work of researchers easier, whether they are developing a drug for a pharmaceutical company, or conducting academic research. In return I want to see more responsibility from researchers in terms of reporting their results. Transparency in clinical trials is in the interests of public trust in medicine and good science. The results of around half of all trials are never made known, and the major-

ity of those are unsuccessful trials. A trial can be carried out repeatedly before it becomes clear that it is ineffective, or even dangerous.

A new EU database will be set up to record all trials carried out in the EU, which will be a fantastic step forward. However, the commission wants just a summary of the results to be made public on the database. I do not think this goes far enough, as summaries can be biased and misleading, and we need to see fuller results to allow for systematic reviews. In my report I proposed that full clinical study reports are published on the database, and I will be holding an event on April 10 to get some more views on the feasibility of this for non-commercial sponsors.

There are over 700 amendments for us to consider in the environment, public health and food safety committee. We are hoping to reach an agreement with the council before 2014. It is crucial that we get some better legislation in place soon to enable and encourage life-saving research. ★

Glenis Willmott is parliament's rapporteur on clinical trials on medicinal products for human use



*"Transparency in clinical trials is in the interests of public trust in medicine and good science"*

# Lessons learned?

All results from clinical trials must be made known, so as to better protect citizens and stimulate research, argues **Michèle Rivasi**

**B**oth before reaching pharmacy shelves and after going on sale, drugs are tested on patients during clinical trials. The purpose being to assess their effects on health, their efficacy in relation to other treatments, the optimum dose at which, and for how long, they should be prescribed.

In the case of drugs already on the market, the starting point is the post marketing licence trial. The clinical trials regulation is intended to encompass all clinical trials, both pre and post-marketing licence, as well as those outside the scope of any, albeit temporary, commercial objective, for the treatment being tested. If, like ecologists, one's primary aim was to ensure patient safety during clinical trials and the reliability of any treatments available at the end of such trials, the new regulation put forward by the European commission to the MEPs is unacceptable as it stands. It places particular emphasis on the competitiveness of the European Union in terms of clinical research and the development of new treatments, but makes no provision for explicit ethics committee consultation for protocol validation upstream, or public access to data resulting from trials downstream, thereby giving rise to a real public health problem.

In the absence of any such guarantees, the pharmaceutical industry can continue to hide any crucial information concerning its products already on the market and we are not safe from a new 'Médiator'. The Servier laboratory had marketed this drug since 1976 as an antidiabetic, however, it came to be widely prescribed as a diet drug. This off-label use allowed Servier to sell its product to a much larger public than that strictly intended for the use covered by the marketing licence. In France, 145 million boxes were sold until the drug

was withdrawn in 2009. Its withdrawal received wide media coverage and followed hundreds of deaths attributed to the secondary effects of Médiator. This means that if Médiator had not been diverted from the use for which its marketing licence had been issued, as was the case with the Diane 35 pill (an anti-acne medication turned into a contraceptive pill), there would not have been so many victims.

In order to avoid secondary effects which could even result in the death of patients, we must know all clinical trial results, whether positive, negative or mitigated. The disappearance into the ether of data from trials which go bad must be avoided at all costs. Firstly, to prevent any such tests from being repeated in future with new individuals who would be put in danger needlessly, and, secondly, to stimulate research based on the knowledge acquired during each clinical trial.

Unfortunately, my proposal for the systematic publication of a full study report at the end of each clinical trial – accessible to all, including any whistleblowers who could be patients, doctors or independent researchers – has been rejected by my colleagues on parliament's industry, research and energy committee. Just like the mandatory involvement of an ethics committee when a clinical trial is to be authorised, to make absolutely sure of the relevance of the protocol, patient informed consent and the latter's compulsory insurance. This vote sends out a very bad signal from MEPs to the citizens of Europe who are fed up with being treated as guinea pigs. It is our hope that the environment committee will prove to be more protective. ★

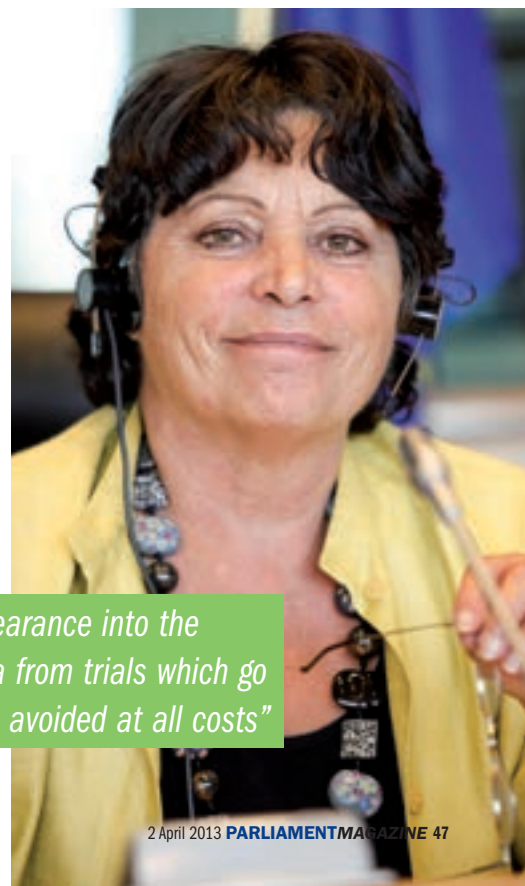
Michèle Rivasi is parliament's industry, research and energy committee opinion rapporteur on clinical trials on medicinal products for human use

## The Médiator case

Médiator (benfluorex) was authorised to treat diabetes but was also prescribed as an appetite suppressant. It was on the market for over thirty years and was licensed and sold in France, Portugal, Luxembourg, Greece, Italy and Spain. Although it gave rise to doubts from 1999 it was not withdrawn in France - its biggest market - until 2009. "Estimates of the number of deaths related to Médiator vary from 500 to 2000", says EP rapporteur Linda McAvan (S&D, UK).

Source: *Europarl*

*"The disappearance into the ether of data from trials which go bad must be avoided at all costs"*



# Clinical Trials Regulation

## Maintain the Spirit of Harmonisation

Michael Doherty, Sabine Atzor, F. Hoffmann-La Roche Ltd.



Following years of public debate and criticism about the current framework on clinical trials the Commission's proposal for a Clinical Trials Regulation represents a step forward to achieve the objectives of the Europe 2020 Agenda for competitiveness and innovation for the pharmaceutical industry in Europe. Key proposals for future success include:

- single submission of the clinical trial application dossier to an EU database,
- single assessment of the respective dossier, with a reporting Member State coordinating input from all concerned Member States, and
- single decision per clinical trial per Member State based on a review both by competent authorities and by ethics committees.

In the ongoing discussions, Roche calls on the European Parliament and the Council to focus on the main intentions of this important piece of legislation which are:

- **Maintain the spirit of harmonisation:** Harmonisation of scientific and administrative requirements for clinical trials between Member States while replacing or amending national rules, is one of the key concepts. It is important that this is fully maintained – any deviation would be detrimental to a joint assessment and contrary to the spirit of the Regulation.
- **Maintain assessment timelines:** The proposed timelines for assessments are competitive with regions outside the EU and would allow for review by both competent authorities and ethics committees. Tacit approval and withdrawal are appropriate mechanisms to ensure that Member States and sponsors comply with these timelines.
- **Support ethics committees:** Roche requests clarification concerning the need for reviews by ethics committees in the Member States for each clinical trial. At the same time, a platform or mechanism for best practice exchange should be established to encourage increased cooperation between ethics committees across the EU.
- **Support excellence building:** The provision for sponsors to propose the reporting Member State should be maintained since this approach is in line with the national Heads of Medicines Agencies' process for excellence building. Roche supports a review of clinical trials applications by the most experienced reviewers.
- **Harmonise approaches for innovative study designs:** The Clinical Trials Advisory Group CTAG, which will be chaired by the European Commission, should coordinate Member State's

interpretation as regards the review of innovative study designs. This would ensure consistency and avoid a delay in the review of such studies due to different approaches.

- **Ensure update with scientific progress:** A clause which allows for timely adaptation of legislative provisions with the ongoing scientific progress of clinical trials is needed. Roche, like other pharmaceutical companies, is currently exploring innovative study concepts such as the integration of social media to bring trials closer to patients in line with existing national legislation. A review of roles and responsibilities of an investigator, the trial participant and a trial site in a cross-border health setting may be required in the future.







- **Support transparency:** Roche supports greater transparency on clinical trial information in the interest of patients and prescribers in accordance with national or regional provisions. In this spirit, Roche has been providing public access to results from clinical trials via the US database *clinicaltrials.gov*, its own database *rochetrials.com* and will do so in the future via the EU database *EudraCT* once it becomes fully operational. Yet, the discussion on transparency related to the Clinical Trial Regulation must not be confused with the discussion on transparency related to application dossiers for a marketing authorisation application:

In the context of the Clinical Trials Regulation, the key intention is to better



inform patients about all ongoing and completed clinical trials, allowing them to follow clinical research of personal interest to them. To protect companies' legitimate commercial interests – particularly before a product has been authorised – lay friendly summary information of any future trial should be publicly accessible. The interpretation of what constitutes legitimate “commercially confidential” information in line with EU transparency legislation should take the authorisation status of a product into account.

Following completion of all required clinical studies, companies submit Clinical Study Reports (CSR) alongside their application dossier for a marketing authorisation. This is regulated by the Pharmaceutical Directive 2001/83/EC and thus clearly outside the scope of the Clinical Trials Regulation. Companies submit all information to the European Medicines Agency (EMA) requested for the approval of its medicines, including CSRs. Roche supports the release of full CSRs for authorised medicines by EMA following consultation with the company to ensure patient confidentiality and the protection of legitimate commercial interests, including intellectual property rights. Roche will provide CSRs on request in cases where EMA is not able to provide them, with the prerequisite that they are on file at EMA.

Release of such documents should only occur following authorisation of a medicinal product for marketing.

Following completion of regulatory reviews in the EU and US, Roche will also enable access to anonymised patient level data from clinical trials which have been submitted together with an

application for a medicine's marketing authorization. Access through a secure system will be subject to the assessment by an independent body to determine the scientific validity of the request and will require an agreement. Roche is currently establishing a process for this and has entered discussions with other companies to see if this approach can be an industry-wide initiative.

## About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit [www.roche.com](http://www.roche.com)

# Striking a balance

Europe needs to strike a balance between transparency and the protection of commercial interests through its approach to clinical trials, writes **Cristian Buşoi**

**T**he decline of clinical trials in the EU in the last decade is a symptom of the lack of competitiveness of the EU in this sector. Patients' access to innovative and affordable medicines requires a boost in medical research and innovation, for which the revision of the European legislative framework on clinical trials is fundamental. We need authorisation procedures which are quicker, simpler and less bureaucratic, but this shouldn't be done at the expense of a volunteer's safety.

On the one hand, it is important to have an EU portal which will be the single-entry point for the submission of applications, a coordinated assessment for those aspects which are common to all member states, ambitious timelines accompanied by the principle of tacit authorisation, which will make the timelines enforceable, as well as simplified and less bureaucratic reporting obligations.

On the other hand, it is crucial to make sure that the ethical assessment is an integral part of the authorisation process, which is an important safeguard to protect volunteers. Member states should be free to appoint the bodies they wish and entrust them with the competences they consider most appropriate, as long as the timelines are complied with. It

should be made clear that this is not a parallel process and that it cannot delay the whole procedure. It is not acceptable for an ethics committee to block the whole procedure by taking too much time to assess a clinical trial.


Another important aspect with regard to volunteers' protection is that of informed consent, and we should have clear rules in this regard. Before giving their informed consent, volunteers, or their legal representatives, should receive all relevant information on the objectives, risks and inconveniences of the trial and sufficient reflection time should be allowed. However, I think the rules on informed consent should be adapted to the situation concerned. For instance, we shouldn't make the rules on informed consent for clinical trials in emergency situations too rigid, because those patients may be deprived of a treatment which may actually save their life.

The new regulation should also enhance transparency in clinical trials. The EU portal and the corresponding database will significantly contribute to this objective. The transparency of results, a topic which received a lot of attention in parliament, should also be tackled. I think it is very important to avoid having emotional debates in this regard rather than taking into account the reality on the ground. We need to balance transparency with the protection of commercial interests through an approach that takes into account the marketing authorisation status.

Before marketing authorisation, a detailed summary of the results which would enable independent researchers to scrutinise them, accompanied by a summary adapted for the general public, should be enough. After marketing authorisation, the initiative on proactive publication of results on which the European medicines agency is currently working should be encouraged provided that it is accompanied by clear rules to avoid any abuse. This was the spirit of my proposals which received the support of the internal market committee.

This regulation is vital for the future of medical research in Europe. Therefore we need to have a thorough and informed debate in parliament about it to come up with pragmatic solutions. In the end, this is all about striking the right balance between the needs of researchers and the protection of subjects. ★

Cristian Buşoi is a member of parliament's internal market and consumer protection committee



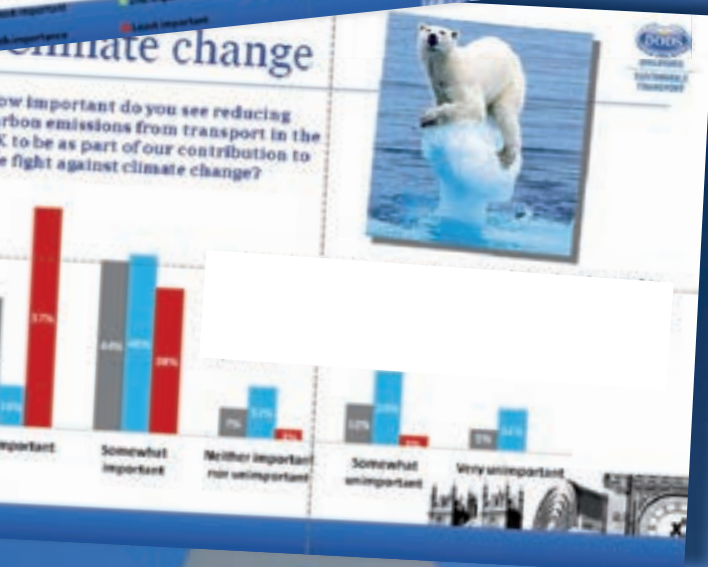
*"This is all about striking the right balance between the needs of researchers and the protection of subjects"*

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