

ENTERPRISE & INDUSTRY *magazine*



**European
SME Week:**
small business,
big ideas

**European Parliament
Elections, June 2009**

**Healthy rules for
pharmaceuticals**



European Commission
ENTERPRISE AND INDUSTRY

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ENTERPRISE & INDUSTRY

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CONCRETE SUPPORT AND ADVICE TO ENTREPRENEURS



Small and medium-sized enterprises hold the key to Europe's future prosperity, in particular as creators of new jobs. Now, more than ever, we need to make business life easier, not just for existing SMEs but also for new start-up firms.

The **first European SME Week** is all about helping SMEs find out about the assistance the EU, as well as national, regional and local governments can offer them. The European Commission is organising the SME Week to raise awareness of the wide-ranging support which is out there and ready to be accessed by small businesses. As our feature article shows,

some **600 events** are taking place all over Europe, **mostly in the week from 6 to 14 May**. Take a look at the website and see what is on near you.

In June, EU citizens go to the polls to **elect** Members of the **European Parliament** (MEPs) for a new five-year term. The Parliament is the only directly elected institution in the EU, and has wide-ranging influence on EU policies, not least those related to enterprise and industry. Four MEPs highlight for us major recent developments and the coming issues in enterprise policy on which the Parliament will play a decisive role. Have your say on how the EU should tackle these and other topics, and do not miss the opportunity to vote in June.

Europe's **pharmaceuticals industry** is world-leading, but it faces constant challenges. The European Commission has adopted a package of proposals to adapt regulation to deal with a 27-Member State

Union in a globalised world. It will improve **patient safety** even further, whilst creating the conditions in which Europe's pharma sector can bolster its **competitiveness**.

The key proposals seek to combat the increase in counterfeit medicines appearing on the market, to improve information available to patients on medicinal products, and to upgrade the system for reporting on possible ill effects of medicines.

Other articles look at the recently launched Erasmus for Young Entrepreneurs, the 2009 activities under the Entrepreneurship and Innovation Programme, Europe's innovation performance, the 'Your Europe – Business' portal and the Enterprise Experience Programme.

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(www.ec.europa.eu/enterprise/e_i) ■



SHINING LIGHT ON SUPPORT TO ENTREPRENEURS



1st EUROPEAN SME WEEK '09

SMALL BUSINESS, BIG IDEAS

Small and medium-sized enterprises can benefit from a wide range of EU, national and regional programmes and policies. The first European SME Week aims to raise awareness of the support available to business. Taking place from 6 to 14 May, it will see around 600 events held in 35 European countries. The SME Week will also promote entrepreneurship, and its value to society, to a broader public.

Small and medium-sized enterprises (SMEs) – in general terms, companies with fewer than 250 employees – are the backbone of Europe's economy. Some 99% of all enterprises are SMEs, and it is in SMEs that most new jobs are created.

The European Union is implementing a wide range of policies designed to create a business environment which encourages entrepreneurs to start new enterprises and to grow existing ones. In June 2008, the European Commission launched the Small Business Act for Europe, with the aim of strengthening support for SMEs even

further, and in particular to ensure that SMEs' needs are taken into account at all levels of policy-making: EU, national, regional and local. The current economic crisis makes the need for SME support all the more vital.

The first European SME Week (1) is being organised by the European Commission to raise awareness of the many policies in place to support SMEs, and to promote the value of entrepreneurship. The Week will see around 600 events taking place all over the 27 European Union Member States and in eight partner countries. It runs from 6 to 14 May 2009 (although some events take

place at other times this year). The European SME Week is one of the key activities of the European Year of Creativity and Innovation.

"The main target audience for the SME Week events is existing and prospective entrepreneurs," explains Kirsi Ekroth-Manssila, Deputy Head of the European Commission's Entrepreneurship Unit. "Our aim is to help them find the support that is available to them, particularly support offered at EU level." In that context, members of the Enterprise Europe Network are organising, or will be participating in, a significant proportion of events during SME Week.

The Secret of Success

Many potential entrepreneurs do not get past their intentions or plans because they lack a role model – someone to whom they can relate who has done it themselves. Often, the real-life demonstration that their dream can be more than just a dream is a significant influence in persuading budding entrepreneurs to develop their plans and implement them.

The Secret of Success is a brochure with portraits of 33 successful entrepreneurs from across Europe (the same ones presented in the SME Experience exhibition). By showing the diverse backgrounds and activities of entrepreneurs, the brochure aims to provide inspiration for the next generation, as well as demonstrating the breadth of their contribution to European society.

The brochure will be available to download from the SME Week website in 21 languages.

Local initiative

Whilst the European 'umbrella' will help promote events and provides a link between them, the emphasis is on local activities, offering tailored information to participants. The events being organised cover a wide variety of themes, with some focused on specific aspects of doing business and others about much more general business and economic themes. The SME Week website allows users to search the calendar, sorting by country and/or by theme to find the actions of most benefit to them.

"The vast majority of events are being held close to the entrepreneurs, to provide them with information," underlines Ekroth-Mansilla. "These are not discussions about

Stepping into the entrepreneur's shoes

A highlight of the first SME Week will be 'The SME Experience' exhibition, which runs from 6 to 9 May, off the Schuman roundabout in Brussels' EU district.

The interactive exhibition aims to show visitors how it feels to be an entrepreneur. They will glimpse the various sensations, hopes and fears, and challenges and rewards experienced by entrepreneurs at the different stages in their company's life. As visitors step from room to room, they will be exposed to new sensations by looking at, listening to, touching and smelling the installations. How does an entrepreneur develop and evaluate business ideas, how do they deal with stress, how do they manage risk, what does the freedom to be 'your own boss' bring, how do they find customers, how do they overcome red tape, how do they negotiate with suppliers, how do they ensure sufficient cash flow... The exhibition will show visitors how entrepreneurs answer questions such as these, which are at the heart of their business. Finding the right answers determines how successful their business is.

After experiencing these different sensations, the exhibition concludes with a set of portraits of entrepreneurs from around Europe. The 33 selected entrepreneurs each have a story to tell about the companies they started. The range shows the different backgrounds, business ideas and models which contributed to their success, underlining the fact that there is no standard entrepreneur 'profile' and that each of them has thrived on their own combination of vision, creativity, persistence and audacity. As they leave, visitors will learn about the measures the European Union is taking to support SMEs and encourage the development of a culture more favourable to enterprise and entrepreneurs across Europe.

The exhibition concept was developed by the European Association of Craft, Small and Medium-sized Enterprises (UEAPME). The aim is to demonstrate the many factors which influence the life of an entrepreneur and their business. It will give potential entrepreneurs the opportunity to consider whether their character is suited to starting a business. More generally, it aims to broaden understanding of the role and importance of entrepreneurs in European society.

During SME Week, the exhibition will host lunchtime events at which visitors will have the opportunity to meet entrepreneurs from around Europe and learn more about EU policies to support them.

The exhibition's final day, 9 May, is Europe Day, and the EU institutions, including the European Commission, will be opening their doors to the public. Visitors to the exhibition may therefore combine their visits and learn more about other areas of EU policy, not least in view of the following month's European Parliament elections.



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policy, between policy-makers, but about concrete support and advice; if you like, our aim is to put the Small Business Act into practice. Even the opening event is something different.”

Taking place in Brussels on 6 May, the SME Week opening focuses on the image of entrepreneurs in the media. In the presence of Commission Vice-President Günter Verheugen and the Belgian Federal Minister responsible for SMEs, Sabine Laruelle, producers from film and television will present clips of their work, and explain their motivations for bringing entrepreneurs to the screen. Discussions, which will be informed by the results of a study on entrepreneurial culture in the audio-visual media, will focus on the different ways in which entrepreneurs are shown on-screen and the resulting image of their activity. The event will explore how various media portrayals of entrepreneurs brings more or less favourable impressions of entrepreneurship to viewers, and in particular how they may encourage budding entrepreneurs to follow that career path. The event will also feature the presentation of the winners of the first European Entrepreneurship Video Awards.

Conclusion, for 2009

The first European SME Week will conclude with a conference in Prague on 14 May, organised jointly by the European Commission and the Czech Presidency of

the EU. Discussions will focus on reducing the administrative burdens on business, and removing barriers to entrepreneurship. Among the speakers will be Edmund Stoiber, who chairs the Commission’s High-level Group of Independent Stakeholders on Administrative Burdens.

On the eve of the conference, this year’s European Enterprise Awards will be presented. Moreover, the winners of the first Best Ideas for Red-tape Reduction Awards will also be rewarded.

Given the number of events being held, the first European SME Week is well on track to be a success. With such a strong response this year, the European Commission is planning to repeat the Week in 2010. ■

Footnotes

(¹) <http://european-sme-week.eu>

Visitors to the site can search the event calendar, watch SME Week videos and sign up for the regular newsletter. During the Week itself, a blog will provide frequent updates from activities all over Europe.

European Entrepreneurship Video Awards

What makes a person take the leap from potential to actual entrepreneur? What does it take, what are the rewards? Every story is different, but entrepreneurs all share the same spirit.

The Entrepreneurship Video Awards is a contest in which European businesspeople have the chance to express their own ideas on business, to show something of their experiences, and to be creative on film. The idea behind the contest is to identify real-life experiences which show what makes the entrepreneur tick, and which can inspire others to follow through on their ideas.

Entrepreneurs were invited to submit short videos on one of three topics – the entrepreneurial spirit, innovative entrepreneurship, and responsible entrepreneurship – up to March 2009. The winners in each category, who will get prizes of up to €3 000, will be announced at the SME Week opening event on 6 May. The winning videos will be used by the European Commission in future activities to promote entrepreneurship, and will be made available on the web.

<http://ec.europa.eu/enterprise/policies/entrepreneurship/video-award/>

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SHARING THE KNOW-HOW OF ENTREPRENEURSHIP

*Experienced business people who have “been there and done it” can provide valuable help for people starting out in business. By helping new or aspiring entrepreneurs spend working time with a host entrepreneur in another country, the EU’s new **Erasmus for Young Entrepreneurs** programme offers access to good advice. It also opens up prospects for new business relationships with partners from different countries in the Single Market.*

In the past two decades, almost 2 million students have followed part of their education in a university in another EU Member State. The Erasmus programme, now one of the major components of the Union’s Lifelong Learning Programme, has grown into one of the EU’s best-known initiatives. Every year, 200 000 students qualify for a grant which enables them to live and study in a different culture and educational system, to make friends from other Member States and explore the different approaches to life and learning which enrich Europe.

Now the European Commission is offering budding and novice entrepreneurs a similar experience, through working alongside an experienced entrepreneur – the owner or manager of a small or medium-sized enterprise (SME) – in another Member State. The Erasmus for Young Entrepreneurs programme kicked off in February 2009. Its €3 million budget will support around 900 such relationships in 2009-2010. Almost double this number can expect to receive support in 2010-2011, with funding of €5 million set aside for an expanded programme.

The programme is just one initiative in the Small Business Act, being undertaken by the EU to encourage entrepreneurship and to create a business and administrative environment more friendly to SMEs.

The Erasmus for Young Entrepreneurs programme addresses the problem that many founders of SMEs lack management experience and key skills. This, coupled with the fact that the vast majority of SMEs operate in only one country, restricts growth. Without doubt, Europe needs more entrepreneurs to develop growth and employment and fulfil the Lisbon Agenda. The new Erasmus for Young Entrepreneurs programme will contribute to this objective. It is part of the European Commission's commitment to place SMEs at the heart of European competitiveness policies to enable them to adapt to globalisation.

Commitment

To participate, new entrepreneurs can be of any age, but they should either be on the brink of starting up a firm, and have already put together a detailed business plan to turn their intention into practice, or have started their own company within the past three years. Some may also be preparing to take over the family business, but still want to get some entrepreneurship experience abroad. The commitment demonstrated to following through their business plan will be critical in assessing their application to participate. So too will be the project they plan to carry out while working with the host entrepreneur.

New entrepreneurs who apply may already have a host entrepreneur in mind, or they can ask the responsible intermediary organisation in their country or region to help them find one through the network of participating intermediaries. Under the programme, organisations such as chambers of commerce and bodies which help start-up firms from across Europe have set up European partnerships to help match up new and host entrepreneurs, and to support them in planning their project and organising the new entrepreneur's time abroad. The European partnerships also have a budget to provide grants to the new entrepreneurs, which contribute towards the costs of their travel and accommodation.

Mutual gain

Once the new and host entrepreneurs are in contact, their first task is to agree on a work plan/project for the young entrepreneur's stay with the host entrepreneur, which could run for as little as a month or as long as six months. In order to allow the entrepreneurs to organise the work plan/project flexibly, the stay can be broken down into several shorter trips over a maximum of 12 months. The key to a successful relationship is that completing the project brings benefits to both parties. The aim is that the new entrepreneur

should work directly with the host, rather than simply observing or working on a discrete project with little contact.

The Commission expects to see, in the longer term, the creation of new businesses and the development of a network of new and experienced entrepreneurs in the EU.

Both parties gain the opportunity to learn about the other's national market, business culture, and possibly get access to innovative ideas. The chance to see at first hand, particularly – but not exclusively – for the new entrepreneur, how another enterprise is run, how the boss takes decisions, how staff work with each other and with the managers/owners, or how they deal with suppliers and customers, provides a basis to evaluate and reassess whether their own way is the most effective or could be improved. Beyond the immediate relationship, both parties can be expected to make new contacts in the other's national market, which can form the basis of new business opportunities in the future.

Each relationship will be unique, with the activities to be undertaken, goals on both sides and the length of the trip all decided by the participating entrepreneurs based on the interests of their respective businesses and their own situations. Whilst in some cases the relationship may lead to an ongoing business partnership between the two entrepreneurs and their companies, in other cases the future relationship after the project is completed is likely to be a less formal one. A network of contacts is a valuable asset for any entrepreneur, and for one aiming to do business in the Single Market, the Erasmus for Young Entrepreneurs programme offers the chance to expand that network very effectively. Indeed, participants will be able to make contact with other participants of the programme, both in their own and other EU countries. The programme will therefore have the bonus of creating a network of European entrepreneurs with an international outlook.

If you are interested in taking part in this new programme, more details on how to apply can be found at www.erasmus-entrepreneurs.eu. ■

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**Erasmus for Young
Entrepreneurs**

INNOVATION AND ENTREPRENEURSHIP CENTRE STAGE

Reflecting that 2009 is the European Year of Creativity and Innovation, the annual work programme for the EU's **Entrepreneurship and Innovation Programme** (EIP) is focusing on enhancing the innovativeness of European enterprises and improving the business environment for SMEs.

With a global financial crisis deepening, and recessionary times on the immediate horizon, there is a growing climate of aversion to risk, which may spell bad news for entrepreneurship and innovation. But, as history has repeatedly shown, the best way out of tough times is to think outside this box and find creative solutions.

Against this backdrop, it is fitting that 2009 is the European Year of Creativity and Innovation, as the EU will need to muster all its powers of innovation to pull out of this crisis rapidly. One major stimulus in this regard is the €2.17-billion EIP, which is the largest component of the Union's Competitiveness and Innovation Framework Programme (CIP).

The EIP's 2009 work programme contains an entire toolbox aimed at unlocking Europe's innovative and entrepreneurial potential. Many of the work programme's 39 measures relate to small and medium-sized enterprises (SMEs), which are a major innovation dynamo and Europe's leading source of jobs.

A credit to the economy

Given the important role SMEs play in venturing into new business frontiers, as well as creating jobs, it is important to tackle the risk that the economic crisis affects their access to finance. The EU has already launched a number of initiatives in this regard and a recent Commission-hosted round table brought together stakeholders to chart a way forward.

The EIP's 2009 work programme has earmarked nearly €144 million, which will be channelled through the European

Investment Fund, to bolster the availability of credit to start-ups and innovative SMEs.

In fact, SMEs are the principal targets of the work programme's main priorities. These include creating an environment favourable to SME co-operation, encouraging innovation and eco-innovation, promoting a culture more

Competitiveness and Innovation Framework Programme (CIP)

The CIP is the European Union's major funding instrument to support competitiveness and innovation, paying particular attention to the needs of SMEs and thus contributing to making the EU economy as a whole more competitive. Running from 2007 to 2013, with an overall budget of €3.6 billion, the CIP has three specific programmes: the Entrepreneurship and Innovation Programme, the Information and Communication Technologies (ICT) Policy Support Programme, and the Intelligent Energy Europe Programme.





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supportive to entrepreneurship and innovation, and administrative reform geared towards facilitating innovation.

One-stop shop

As part of its effort to provide SMEs with comprehensive assistance, the EIP will continue to support the Enterprise Europe Network in 2009, which provides companies with support at their 'doorstep' in more than 40 countries.

Launched last year as the successor to the earlier Euro Info Centres and Innovation

Relay Centres, the Enterprise Europe Network describes itself as "speaking the language of business". The network provides a broad range of information and support services, including helping SMEs find technology and business partners; providing information on access to different types of SME finance; identifying project funding opportunities; and bringing SMEs into policy-making by acting as a conduit to the European Commission for their views.

This year's work programme will have a particular focus on enterprise matchmaking events, environmental services for SMEs, and the setting up of a network of ambassadors for female entrepreneurship, as well as SME panels to gauge the opinion of entrepreneurs on relevant EU policy matters.

Embedding innovation

Deepening and broadening Europe's capacity to innovate is an integral component of the EIP and the 2009 work programme reflects this. This year, it has set aside nearly €60 million to stimulate all forms of innovation. Measures in this area include support for 'lead markets' and the Europe INNOVA and PRO INNO Europe networks.

Europe INNOVA, which acts as a focal point for innovation networking in Europe, aspires to inform, assist, mobilise and bring together the key stakeholders in the field of entrepreneurial innovation. PRO INNO Europe is a focal point for innovation policy analysis, learning and development in Europe. In 2009, it will organise regular Innovation Information Days.

The EIP also continues to support the development of green technologies, with more than €60 million dedicated to eco-innovation, including €27 million for first application and market replication projects. This part of the programme is addressed mainly to companies which have developed an environmental product, service, management practice or process which has a proven track record, yet is not fully marketed due to residual risks. The EIP will help to overcome those barriers to further market penetration and turn these products and processes into Europe's future eco-innovation successes!

In 2009, the EIP is also channelling some €20 million into creating a culture conducive to greater innovation and entrepreneurship which will support, among other things, the acceptance and implementation of the Small Business Act. ■

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ENTERPRISE POLICY AND THE EUROPEAN ELECTIONS

The European Parliament elections in June are the opportunity for European citizens to choose their representatives, who will shape EU policies for the next five years. The new, or re-elected, Members of the European Parliament will have a major influence in determining how EU legislation supports entrepreneurs and enterprises. In this article, we hear from several MEPs on the key issues in the enterprise and industry field.

In the first week of June 2009 (¹), around 375 million voters across the 27 European Union Member States have the chance to vote on who they want to see represent them in the European Parliament for the next five years. In the EU's only directly elected institution, the Parliament's Members (MEPs) represent almost 500 million EU citizens in the EU's law-making process.

The Parliament is the Union's joint law-maker, alongside the Council (made up of representatives of each Member State government), in the so-called co-decision procedure used to adopt the majority of EU legislation. MEPs can, and do, vote to amend the European Commission's legislative proposals, and proposals can only come into law when Parliament and Council agree on the complete text. Who you, and your fellow citizens, elect as MEPs therefore has a direct impact on future EU laws.

Issues to address

EU policies and legislation cover a wide range of issues directly relevant to industry, to enterprises and to entrepreneurs. *Enterprise & Industry magazine* asked several MEPs from the outgoing Parliament what they believe were the Union's biggest

achievements in the enterprise field over the past five years, and what they see as the key challenges for the coming five.

According to Jorgo Chatzimarkakis, a German Liberal, who drafted Parliament's report on the Competitiveness and Innovation Framework Programme, "creating awareness and momentum for the needs of SMEs was the most important achievement in the last five years, especially the appointment of a special envoy [for SMEs] by Commissioner Verheugen, and discussions on the 'Small Business Act'. In the next Parliamentary term, he emphasises, the EU needs to act on administrative burdens: "SMEs suffer more than others from red tape. Here, we need concrete steps to lift several bureaucratic burdens."

Edit Herczog, a Socialist from Hungary, drafted the European Parliament's report on the Small Business Act. 'The Small Business Act' opened up the way for unrestricted growth of SMEs by entrenching the 'Think Small First' principle in policy-making at all levels. ... Small and medium-sized enterprises have for some time been recognised as the backbone of EU economy. We should also call on the Member States swiftly to transpose and implement the Services Directive, paying special attention to the interests of SMEs. That is the way to strengthen our European economy and market."

Looking to the next five years, she says, "I consider information and communication technology and the digital turnover as an integral part of development and prosperity of the European economy and of the whole society. I believe that Europe's role is to stand for a strong knowledge-based society. Therefore we need to be ready for the digital switch-over by creating the best European environment for that, by continuing to give strong support for European enterprises, especially SMEs, and by building a powerful and co-operative transatlantic market."

Heidi Rühle, a Green MEP from Germany, says that, "We have been particularly keen to improve surveillance and control procedures in order to enhance product safety and quality, taking into account environmental impact. This issue was central in the 'goods package' but also, for example, in the new Directive on toy safety. We have welcomed the Directive on unfair commercial practices too, in order

to protect consumers better, in particular the most vulnerable ones. The agreement on the Ecodesign Directive and the adoption of first implementing measures on standards for environmental performance have also been significant accomplishments."

For the next five years, "The biggest challenge for EU enterprise policy will be to contribute in managing the conversion of European industry towards sustainability. This is necessary to cope with the environmental and climate change challenges, and also to safeguard business chances in the new green industrial revolution. Attention has to be paid [to ensure] that the new Services Directive does not lead to social and environmental dumping. I would in particular welcome a systematic earmarking of funds for SMEs, as was achieved in the research programme thanks to the Greens."

French Christian Democrat, Jacques Toubon, who drafted Parliament's report on the Single Market Review, says the biggest achievement "is the Services Directive, which allows establishment, facilitates cross-border provision of services, and enhanced quality services, establishes a system of administrative co-operation between Member States and strengthens the rights of users of services. In addition, it fully respects the social rights of workers and preserves national legislation on a huge number of issues. In the meantime, this Directive can be an effective tool to help modernise national legal frameworks, eliminate barriers to the Internal Market for services and help achieve the Lisbon goals. It is a masterpiece of the Internal Market."

In the next five years, he underlines the need to create "an industrial policy based on innovation, with emphasis on the need to quickly conclude negotiations on the Community patent! In addition, we need to encourage the growth of European small and medium-sized enterprises by implementing the Small Business Act; by placing the 'Think small first' principle at the heart of Community policies through a binding instrument."

It's your choice!

In the coming years, the EU will be continuing its efforts to make Europe a supportive business climate, to create better jobs for its citizens, to respond to challenges such as globalisation, environmental degradation and depletion of natural resources, including energy sources. Moreover, the Union will be acting to assist economic recovery after the current economic slowdown. MEPs will be taking decisions on these and many other important areas, so find out the candidates' positions and have your say on the policies we need by voting. ■

Footnotes

(¹) The elections take place between 4 and 7 June, depending on the Member State. Results are declared after the polls have closed in all Member States on 7 June.

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www.europarl.europa.eu/elections2009





HEALTHY RULES FOR PHARMACEUTICALS

A new European Commission package of proposals prescribes a course forward for the pharmaceuticals sector, so as to address the challenges it is facing, while ensuring a high level of protection of public health.

Europe's pharmaceuticals sector – one of the largest, most innovative and most competitive in the world – is crucial both to the health of EU citizens and to the well-being of its economy. The Europe-based pharmaceutical industry is one of the best performing European high-tech industries, employing around 640 000 people. The sector accounts for 18% of the EU's total R&D investment and around 5% of the Union's manufacturing value added, with a positive trade balance of €43.5 billion.

And things could well get better. Promising opportunities abound, such as emerging technologies, in particular biotechnology, and potentially revolutionary treatments, which can support the sector, as well as improve public health.

Challenges ahead

Nevertheless, the European pharma industry, once the leading light in global pharmaceutical innovation, is facing a number of major challenges, such as the gradual corrosion of its competitive edge and, despite research expenditure increasing, it has lost ground in the innovation stakes relative to its major rivals. For instance, between 1990 and 2006, R&D investment in the United States expanded fivefold, while in Europe it grew less than threefold. There is also an emerging trend in which R&D facilities are shut down in Europe in favour of Asian locations. Moreover, the past five years have seen Europe lose its status as the leading inventor of new pharmaceutical molecules in the world.

More broadly, despite the fact that EU Member States tend to have the most efficient, comprehensive healthcare systems in the world, healthcare costs are rising. With drugs accounting for 16% of European health expenditures, rising costs are partly due to the high price of patented drugs, the rapid increase in the consumption of drugs and limited competition from generic medicines.

In addition, patients still suffer from unequal access to medicine, particularly in the Union's newer Member States, and there are a rising number of public health threats. Paramount among these are avian influenza, or bird flu, and counterfeit medicines. Worryingly, there is also growing promotion of fake 'life-saving' drugs, such as medicines to treat cancer and heart disease, and counterfeits are slowly finding their way into the conventional supply chain. >>

Well-informed patients

Once upon a time, it was not regarded as important that patients should understand the treatment they were prescribed by their doctors. Nowadays, EU citizens expect to have access to information on medicines and treatments and to be more actively involved in the decisions regarding their health. With the increased use of the internet over recent years, ensuring the reliability and quality of on-line information has become essential.

Regulatory action at EU level will benefit Europeans by ensuring that they have access to information which is consistent and of a high standard, boosting the supply of non-promotional information that is in line with Union legislation. The Commission's proposal for a Directive on information to patients has three key elements: defining the type of information that can be disseminated about prescription drugs (approved product characteristics, factual information about the effects of the medicine, etc.); the communication channels that can be used and the barring of unsolicited communications; as well as outlining harmonised quality criteria for the information provided.

Combating counterfeiting

Bogus and counterfeit drugs are generally unsafe, inefficient, or low quality and therefore pose a direct threat to human health. The number of fake medicinal products intercepted across Europe is steadily rising. In addition, there is a worrying shift away from so-called 'lifestyle' drugs and towards life-saving medicines, which multiplies the risks to patients. Moreover, in order to shift more volume, counterfeiters are increasingly channelling their fake products through the legal supply chain.

In its proposed Directive on 'falsified medicinal products', the Commission includes a legal basis to render mandatory identification, authenticity and traceability features obligatory; strengthening the supervision of actors in the distribution chain, including mandatory audits of wholesale distributors; and measures to ensure that imported active pharmaceutical ingredients have been manufactured in accordance with EU safety standards.

Factors in the equation

The challenges facing the European pharmaceutical sector can be divided into a number of factors: economic, policy, scientific, as well as societal and demographic.

The forces of the global market place and the growing cost and complexity of developing new drugs have led to the emergence of new business models which focus on product pipelines, more collaboration between industry and academia, partnerships between giant firms and innovative start-ups, and the increased prominence of clusters. Scientific breakthroughs, such as regenerative medicine, are set to revolutionise healthcare and the pharmaceutical industry, pushing the sector away from the 'blockbuster drug' model, towards a more tailored approach to medication.

To protect public health and well-being, pharmaceutical markets in Europe tend to be highly regulated. Despite attempts to promote regulatory convergence, there are discrepancies in the implementation of EU rules, leading to a somewhat uneven playing field. Moreover, the bureaucratic burden on pharmaceutical companies has risen considerably over time.

In addition, the EU drugs market remains fragmented due to the divergence of national pricing and reimbursement policies, as well as the absence of a pan-European patent. Despite these shortcomings, however, the Union's legal and non-legal

framework has also provided strong incentives for innovation and strengthened the sector's competitiveness.

Over the coming years, three socio-demographic trends will have a major impact on the sector: the greying of the European population, which will exert extra pressure on public health budgets, the growing empowerment and involvement of European patients, and the ethical aspects raised by new technologies.

The case for action

The common nature of the challenges and opportunities facing the European pharmaceuticals industry provides a powerful case for coordinated EU action. Although the EU Treaty reaffirms that the health of citizens is primarily a national prerogative, it also makes provisions for regulating pharmaceuticals to protect public health and complete the Internal Market.

The Commission's proposed pharmaceuticals package seeks to create an overarching strategic framework which addresses all the issues facing the sector in a comprehensive fashion. The package's main policy objective is to ensure that European citizens can benefit from a competitive industry that generates safe, innovative and accessible medicines. This will be done through a mixture of legislative measures and stepping up political and international collaboration, in particular between regulators.

"We are convinced that the pharmaceutical package serves the double function of protecting public health and improving the functioning of the single market," says Martin Terberger, Head of the Pharmaceuticals Unit in the European Commission's Enterprise and Industry DG. "The package will be decisive in the debate between the EU Institutions on the future of the pharmaceutical sector."

Moreover, the package aims to fill certain gaps in the current legislation. European citizens need to be better protected and better informed about pharmaceuticals. With this new package, the Commission is addressing these gaps with proposals to strengthen the EU system for monitoring the safety of medicines (the 'pharmacovigilance' system); to improve preventive measures to stop counterfeit medicines from entering the legal supply chain; and to ensure that all EU citizens have fair access to objective and reliable information about the medicines which are available to them. (See boxes for more details on the three legislative proposals in the package.)

An impact assessment of the potential effects of coordinated European action found that: "New EU actions can have an important economic and competitiveness impact by applying the principles of 'Better Regulation' to streamline the regulatory



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Vigilance always pays

Although drug approval procedures in the EU are stringent and require years of testing before a treatment can be brought to market, there is always the chance that unforeseen adverse reactions will be detected after a medicine has been authorised. Since the full safety profile of medicinal products can only be known after they have entered the market, the EU has strict so-called 'pharmacovigilance' rules in place which act as a kind of early-warning system for any emerging risks.

Despite the general effectiveness of this system, a 2004 independent review uncovered a number of shortcomings which the proposed legislation on pharmacovigilance aims to address. Among other things, the proposal more clearly defines the responsibilities and roles of the various actors, rationalises EU decision-making on drug safety issues, and strengthens the pharmacovigilance systems of pharmaceutical companies.

environment and simplify it without putting public health at risk... Another area where strong efficiency gains may be harvested relates to the optimisation of the network of medicines authorities and the minimisation of the regulatory burden it generates."

It went on to note: "At the international level, major positive economic benefits may be realised if convergence with other big markets (especially the USA) can be achieved." ■

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EUROPE'S INNOVATION PERFORMANCE

The latest European Innovation Scoreboard gives positive news for the Union as a whole and for most Member States. But whilst the situation is improving, there are still big gaps in performance with our main competitors. The parallel European Innovation Progress Report takes a more qualitative look at Europe's innovation policies, and provides pointers to successful measures in different Member States.

Overall, the EU is improving its innovation performance, and continuing to close the gap with the USA and Japan. That is the headline message of the eighth annual European Innovation Scoreboard. On the other hand, whilst some EU Member States continue to improve their individual performance, others still have significant efforts ahead of them. It should also be noted that the latest Scoreboard is, in the main, based on data

covering the years 2006 and 2007, and so the effects of the current economic crisis on innovation performance have yet to show up in the indicators. Continuing their efforts to develop more comprehensive measurements of innovation performance, the team behind the Scoreboard have revised their methodology and sought out new indicators. The 2008 Scoreboard uses measures for a range of innovation dimensions:

- availability of human resources, and public and private finance – 'enablers', outside individual firms;
- investments by firms, collaboration between firms and between firms and public sector organisations, entrepreneurial effort, intellectual property rights generated through innovation – 'firm activities', or the direct efforts of firms to innovate; and
- firms which have brought innovations to market, or introduced them to their own processes, and the economic effects of innovation – 'outputs' of firms' innovation.

Progress

The Scoreboard classifies EU countries in four groups, based on a composite 'summary innovation index'. These are the *innovation leaders*, whose performance



is well above the EU-27 average; the *innovation followers*, whose performance is less strong but still above the EU average; *moderate innovators*, with performance below the EU average; and *catching-up countries*, which although well below the EU-27 average are improving their innovation performance.

Current innovation performance gives only a snapshot, however, and the Scoreboard also shows each country's progress over a five-year period. All except one have improved their innovation performance during those five years. In general, the catching-up countries show the fastest growth with the innovation leaders showing the slowest, although certain countries in each group have lower growth performance than their counterparts.

The trend to convergence is confirmed when the change in innovation performance is broken down into the seven innovation dimensions. The strongest drivers of improved performance in all four groups are finance and support, human resources, and throughputs (intellectual property rights generated). On the other hand, all four groups show a decline in the 'innovators' dimension, which equates to the numbers of firms reporting that they have introduced innovative products or services to the market, or innovative processes in their operations.

Comparing EU innovation performance with that of the USA and Japan, the Scoreboard shows the gap closing on both. Whilst progress in catching up with the USA seems to have slowed, according to the latest year's data, progress against Japan – albeit the gap is wider than that with the USA – remains steady. New for 2008 is the Global Innovation Scoreboard which measures EU countries' performance against that of other major R&D spenders. It shows that the EU as a whole performs better than the major emerging economies. Moreover, a range of EU Member States were amongst those which improved most in the period 1995-2005.

Year of Creativity and Innovation

2009 is the European Year of Creativity and Innovation, and the Scoreboard team developed a new 'creativity, design and innovation scoreboard'. The results show a positive link between levels of creativity and levels of R&D and design activity, and likewise with increased levels of innovation. The Trendchart team also looked at policies to encourage design and creativity across the EU and found that these are predominantly driven at local level and highly dependent on local socio-economic contexts.

Policy review

Besides the Scoreboard, another PRO INNO Europe activity is the Inno Policy Trendchart which builds up knowledge of national and regional innovation policies, and analyses them with a view to offering policy-makers leads to develop new policies based on experiences elsewhere. A network of correspondents in the 27 Member States and six associated countries, as well as six major global competitor countries, analyses the development of innovation policies.

The annual innovation progress report offers a summary of their work, in particular the key challenges each country faces and the effectiveness and appropriateness of policy responses.

The analysis, based on the same four country groupings as outlined in the Scoreboard, shows the different challenges they face and the different policy approaches they are taking to address them. In this year's progress report, the Trendchart team have analysed each country's position from the perspective of failures in the innovation system: in markets, in firms' capabilities, in institutions, blockages in networks, problems in regulatory frameworks, and in policy-making. Broadly, policy in the moderate innovators and

catching-up countries focuses support at the company level, to tackle capability failures, while in the more advanced countries it targets predominantly network failures. Although it appears that catching-up countries and moderate innovators are aware of the institutional failures in their innovation systems, their policies have yet to fully address them.

The report also looks at innovation governance. Whilst the top performers have all developed strong evidence-based policy-making, there seems to be room for improvement in the coordination mechanisms between the various bodies involved. Experience shows the relationship between public and private sectors is critical, and that innovation policy develops best through continually learning and raising ambitions.

Stepping up innovation has been identified as one of the means to recover from the economic crisis. To do so successfully will require a leap forward in innovation policy. Resources need to be shifted to broader public-private partnerships which stimulate demand-driven innovation. ■

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'YOUR EUROPE' PORTAL HELPS BUSINESS CROSS BORDERS

The 'Your Europe – Business' portal gives entrepreneurs and company managers easy access to information on all aspects of doing business in each EU Member State. Recently relaunched with an extended range of information, the site aims to help businesses take advantage of opportunities to trade and offer their services in the Single Market.

© Andrey Volodin

What permits do I need to sell my products in another Member State, how can I set up a branch office, how do I register to contribute to social security for my new employees there, what grants could I apply for to help get the business off the ground? Questions such as these are typical for any European small or medium-sized enterprise looking to expand its business into another Member State. Finding the answers can be, at best, time-consuming and, at worst, so difficult that the search is abandoned.

The European Commission and national authorities established the 'Your Europe – Business' portal in 2005 to help businesses find answers to just this sort of question. The portal allows users to search by topic and by country, leading them quickly to information on their rights and obligations, and on administrative procedures in each EU country. Significant added value comes from access to e-government services which allow many formalities to be completed on-line – before even leaving the home country. To help overcome language barriers, which can hinder access to other EU countries' markets, the portal offers multilingual support. The information is provided and maintained by experts from the European Commission and national authorities.

In 2008, a survey of users and potential users of the site identified a number of improvements and subsequently the site has been redeveloped and relaunched. The survey confirmed the widespread need for access to information on doing business in the Single

Market. Topics of most interest included access to finance, starting a business, market information and taxation. The survey also confirmed that the internet is the first port of call for the majority of respondents when looking for information of this nature, and so the value of the portal, and the need to increase its visibility amongst the target group, is clear.

'Your Europe – Business' ensures users have easy and comprehensive access to information on their rights to do business in the Single Market and their obligations when doing so. The country-by-country, specific information enables users to determine the administrative steps they need to follow to take up a business opportunity in a given country which, can often be completed on-line.

Users of the portal are also encouraged to make contact with their local partner in the Enterprise Europe Network and other business support organisations, who can help solve particular problems. ■

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TAKING OFFICIALS TO THE HEART OF THE ECONOMY

A programme giving officials from the Enterprise and Industry DG the chance to spend a week in a European SME is improving understanding on both sides: the visit offers officials a different perspective on their work, while companies can gain a better insight into EU policies.

The staff of the European Commission's Enterprise and Industry Directorate-General have the job of developing measures to encourage the creation of a more business-friendly environment in Europe. For them, having first-hand knowledge of the way business works, of the pressures people at all levels in firms face, and of the dynamics which influence success or failure, is vital.

The Enterprise Experience Programme was launched in 2006, with the aim of enabling staff in the Enterprise and Industry DG to spend a period of time – generally a week – in a European small or medium-sized enterprise (SME). So far, 108 officials, including several senior managers, have spent time in around 150 host SMEs, with visits reaching all corners of the EU. Officials are matched with enterprises where there is a common language for communicating with each other. Participating officials can nominate industrial sectors of particular interest to them, and where possible they will be hosted by a firm in one of those sectors.

Small Businesses welcome officials

Enterprises from a wide range of sectors have applied to host an official. Some are primarily interested in finding out about EU initiatives, in particular how to access funding. Some have seen hosting an official as a means to generate publicity, in the local press for instance. More recently, enterprises have shown a desire to communicate with the Commission about the actions they would like to see taken to develop enterprise policy. And finally, some are simply curious, seeing the chance to host an official as something out of the ordinary.

The programme for each visit is agreed in advance by the official and the company concerned. Different visits have taken very

different forms: in some, the official has shadowed a single person throughout the week, others have spent time in several different departments. Some visits have kept the official within the firm throughout their time, while others have spent part of the time out on the road with their host, visiting customers, suppliers and even business-support services.

Broadening horizons on both sides

For the officials, the visit gives them a different perspective on their work, and offers them new experiences. In fact, many officials in the Enterprise and Industry DG worked in the private sector before joining the Commission, but they too have the opportunity to refresh their memories and see a different business culture from that of their past experience. Officials returning from visits have valued the personal exchange with the host companies' staff highly, as well as the opportunities for direct contacts with the business world.

Maarit Nyman, from the SME Policy Development Unit spent a week with POSEK, a regional development agency in Pori, western Finland, in September 2008. She explains that "the one-week experience provided a great opportunity to meet with entrepreneurs, public authorities and SME support organisations, and learn about their activities". Likewise, they were keen to host an official, and afterwards Kari Hietala, special advisor in POSEK, said that "the visit opened up a fresh and wide view of current EU actions for SMEs."

Is your enterprise interested in hosting an official? Discover more details on the website where you can apply to the programme. ■

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NEWS IN BRIEF



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STRENGTHENING EUROPE'S CHEMICALS INDUSTRY

The High-level Group on the European chemicals industry has published a report with 40 recommendations aimed at reinforcing the industry's competitiveness and its contribution to sustainable development. The continuing prosperity of the industry requires more innovation and research, responsible use of natural resources and fair access to raw materials, and open world markets, the report concludes.

www.ec.europa.eu/enterprise/chemicals/hlg/hlg2/hlg_index.htm

CORPORATE SOCIAL RESPONSIBILITY

"I strongly believe that the companies to lead us out of the recession will be those which consider corporate social responsibility (CSR) as part of their core business strategy," said Commission Vice-President Günter Verheugen, addressing the CSR Forum on 10 February. "I have argued for some time that Europe can only flourish... if enterprises are trusted, and actually trustworthy, and valued for their contribution to society. This argument has never been more relevant than it is today."

www.ec.europa.eu/enterprise/csr/forum_2009_index.htm



© Amanda Rohde

GMES DELIVERS DIGITAL MAPPING TO IMPROVE LAND USE

A first group of 185 EU cities are now covered by data sourced from satellite photos. To cover all EU cities by 2011, the Urban Atlas project provides up-to-date data to enable cities to improve their land-use planning and address problems such as flood risk, the impact of climate change and missing infrastructure. Developed through the Global Monitoring for Environment and Security (GMES) initiative, the project is delivering more cost-effective digital mapping than ever before.

www.ec.europa.eu/gmes



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SPACE SURVEY

The European Commission is seeking the views of children – aged from 6 to 14 – on European activities in space. The internet survey (open from 8 April to 1 June 2009) asks children about their expectations of current and future space activities, in particular in the field of space exploration.

<http://surveys.publications.europa.eu/formserver/space>



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COMPANY REGISTRATION PROCEDURES IMPROVE

During 2008, initiatives in several Member States have brought the average time needed to register a company down to nine calendar days (from 12) and the average costs to €463 (from €485). Moreover, there are now 18 Member States with one-stop shops for company registration.

www.ec.europa.eu/enterprise/entrepreneurship/support_measures/start-ups



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» Find out more...

For information on further recent activities and policy developments related to Enterprise and Industry, visit our website:

www.ec.europa.eu/enterprise

BETTER REGULATION STRATEGY HELPING SMES

The European Commission's Better Regulation strategy is making concrete steps in reducing the administrative burden on firms, in particular SMEs. The third strategic review of Better Regulation, adopted in January, shows that around 1 300 legal acts (or one-tenth of the Union's law book) have either already been scrapped or the legal process to do so is under way. The estimated cost saving as a result is around €30 billion. The Commission has identified 81 further measures which will be ready to be taken up by the new Commission, from 2010. Moreover, some 21 Member States have now launched their own Better Regulation programmes, cutting down the administrative burden due to national rules.

www.ec.europa.eu/governance/better_regulation



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UPCOMING EVENTS



● **EU Finance Day for SMEs,** 28 April, Helsinki; 12 May, Prague; 16 June, Dublin; 30 June, London

Finance Days for SMEs continue their mission of informing a wide range of entrepreneurs and managers from smaller firms of the opportunities to obtain funding through the EU's financial instruments for SMEs. The events will introduce participants to the local organisations through which they may access the instruments, and will feature discussions on good practice in obtaining finance based on SMEs' experiences.

www.sme-finance-day.eu

● **European Enterprise Awards,** 13 May, Prague

The 2008/09 European Enterprise Awards will be presented to the winning regions in five categories at a ceremony organised jointly by the European Commission and the Czech Presidency of the EU under the umbrella of the SME Week. Thirteen shortlisted regions will present their projects in an exhibition alongside the ceremony. The award categories are entrepreneurship promotion, red-tape reduction, enterprise support, investment in skills, and responsible and inclusive entrepreneurship.

www.ec.europa.eu/enterprise/entrepreneurship/smes/awards

● **Conference on CLP,** 17 June, Brussels

The new Regulation on classification, labelling and packaging of substances and mixtures (CLP), which aligns existing EU legislation

to the United Nations Globally Harmonised System (GHS), was adopted in December 2008. The European Commission is organising a conference to inform companies and regulatory authorities about the new Regulation, and in particular to provide practical information on the steps needed to ensure compliance.

www.ec.europa.eu/enterprise/reach/information/events

● **High-level meeting on space exploration,** 23 June, Prague

The meeting will bring together key institutional stakeholders from the EU, the European Space Agency and their respective Member States, as well as representatives of third countries active in space co-operation, and should allow for in-depth political discussion of the main challenges ahead.

www.ec.europa.eu/enterprise/space

● **Employment Week 2009,** 24-25 June, Brussels

This year's Employment Week, the 16th, will look at how human capital is the key to growing Europe's economy, and at the preparations which need to be made now to ensure the current downturn is curtailed. Discussions will cover the issue of change and restructuring, assessing strategies for skills development, and looking at how the labour market is being altered by the current economic crisis. Each session will include a range of concrete examples of good practice and innovative solutions to skills development.

www.employmentweek.com

ENTERPRISE & INDUSTRY *magazine*

The *Enterprise & Industry* on-line magazine provides regular updates on policy development, on legislative proposals and their passage to adoption, and on the implementation and review of regulation affecting enterprises. Articles cover issues related to SMEs, innovation, entrepreneurship, the Single Market for goods, competitiveness and environmental protection, better regulation, industrial policies across a wide range of sectors, and more. In short, it addresses all EU policies under the responsibility of the European Commission's Directorate-General for Enterprise and Industry.

Three times a year, the best of the on-line articles, together with a new feature article, are presented in the printed edition of the magazine. You can subscribe to receive the magazine – in English, French or German – free of charge by post. Visit the website and subscribe on-line.

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