ISSN 1680-0516

Enterprise Europe

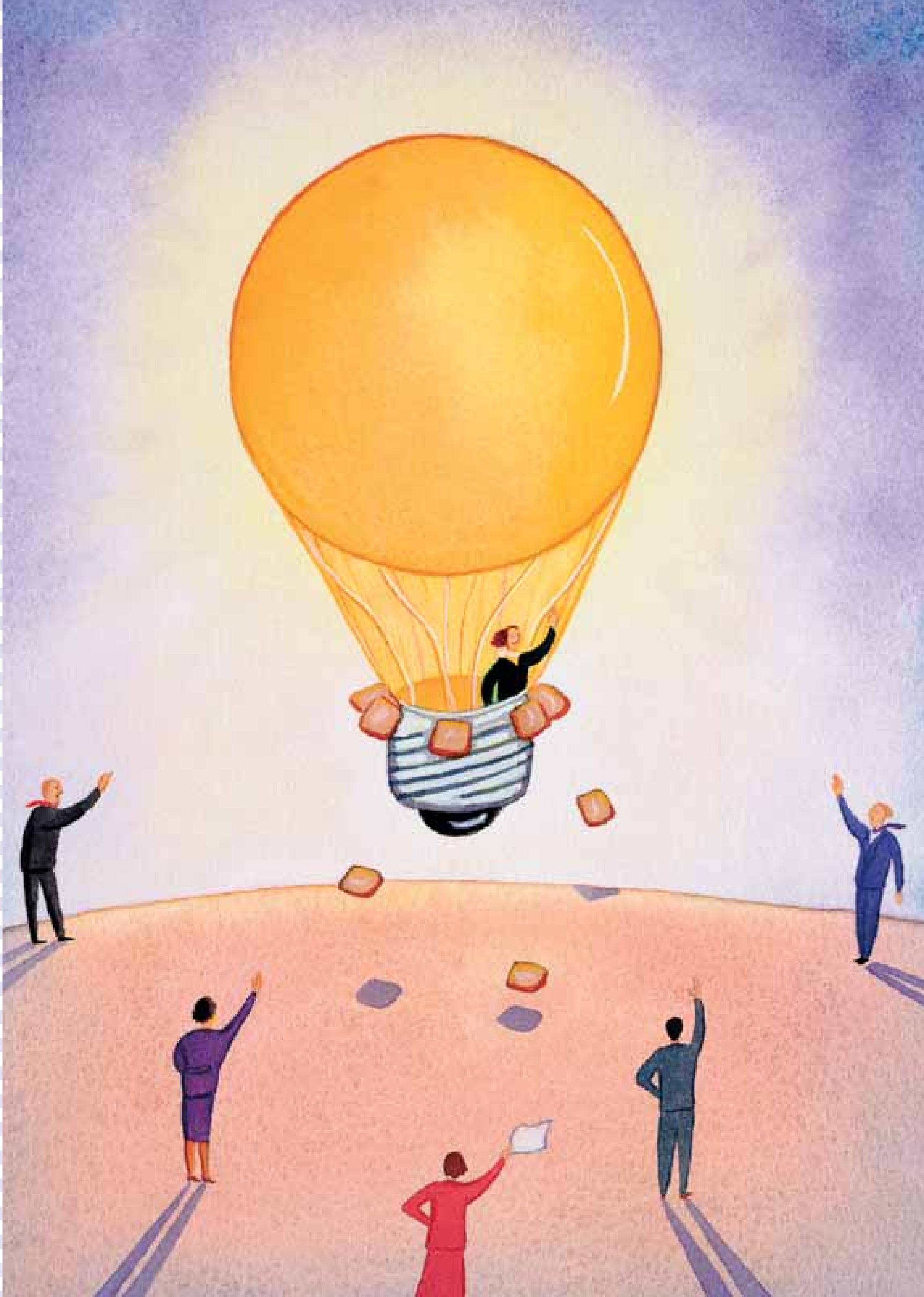
Enterprise policy news and reviews

Published by the European Commission's Directorate-General for Enterprise and Industry

March 2007 | 24

COMPETITIVENESS

Delivering Better Regulation



European Commission

ENTERPRISE EUROPE

Enterprise Europe provides clear insights into European Commission thinking about enterprise and industrial policy. Its in-depth articles offer up-to-date commentary on how we are working with the business community to help develop innovative, competitive and responsible enterprise in Europe and with Member States in implementing the Lisbon strategy in our Partnership for Growth and Jobs.

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Communication and Information Unit
Directorate-General for Enterprise and Industry
European Commission
B-1049 Brussels

Tel. (32-2) 29-66549
Fax (32-2) 29-91926
enterprise-europe@ec.europa.eu

Editor: Hugh Barton-Smith

Photographs and illustrations for this edition were supplied by Getty images and the European Communities.

Catalogue no: NB-BH-06-024-EN-C

Among the further articles available online:

SECTORS

ANIMAL TESTING: EUROPE GOES ALTERNATIVE

Developing alternative methods that can reduce the use of animal testing is a moral obligation. Under certain pieces of European legislation, it is also a regulatory requirement. The European Commission, seven industry sectors and individual companies are working on ways to replace, reduce and refine existing animal tests.

SINGLE MARKET

IMPROVING THE FREE MOVEMENT OF GOODS

A series of articles examining the propositions tabled by the European Commission on 14/02/2007. The measures aim to let the internal market for goods function more smoothly, making it easier for companies, particularly small and medium-sized enterprises, to market products in the European Union while assuring a high level of safety and quality. For industrial goods already subject to EU legislation a new system of market surveillance builds on the existing procedure for consumer products, cooperation between national accreditation bodies will be reinforced and new rules introduced to enhance confidence and trust in the CE marking. Strengthened procedures to enforce the EU principle of mutual recognition will better enable companies to export products that they are entitled to sell on their own domestic market to other EU countries. Finally, guidance on rules for registering cars originating in another Member State will help simplify the currently burdensome procedures for type-approval and registration.

ENTREPRENEURSHIP

European Enterprise Awards

This inaugural competition to honour public initiatives that promote entrepreneurship attracted over 400 entrants from regional and local authorities across the continent. At the prize-giving ceremony in Brussels in December, winners in the various categories came from as far afield as Germany, Austria, Belgium, Italy and Portugal. The top prize went to a project joining together 36 public organisations and entrepreneurs in central Finland.

Finnish Minister of Trade and Industry Mauri Pekkarinen, representing the Finnish Presidency of the European Council, Michel Delebarre, President of the Committee of the Regions and host of the event, and Vice-President Günter Verheugen, Commissioner for Enterprise and Industry, are joined on stage at the prize-giving ceremony by the winners of the European Enterprise Awards.

The European Enterprise Awards have several aims. They represent recognition of the many innovative local initiatives which exist to promote economic growth and employment within the Union. They provide an opportunity to spread good practice, offering public authorities and small businesses a showcase of successful ideas which they may be able to adapt to their own circumstances.

They are also intended to raise awareness of the added value of entrepreneurship within the market economy and to encourage and inspire potential entrepreneurs.

Although only in its first year, the competition sparked widespread interest, demonstrating the sheer diversity of schemes which public institutions and businesses

Article continues page 6

JURY'S GRAND PRIZE

Y4 Committee, Finland. The project, which began in 2003, is designed to motivate people to be innovative and become entrepreneurs, while applying ethically sustainable values. It involves local businesses, elected officials, civil servants, educational institutions, students' development companies, parishes and others. The name comes from four Finnish words, each beginning with Y, meaning 'Promote Entrepreneurship in Society by Cooperation'.
www.y4.fi

ENTREPRENEURIAL TRAILBLAZER AWARD

- **Winner:** Ministry of Economic Affairs, Baden-Württemberg, Germany, with its online portal 'ifex' – a German acronym for an initiative for start-ups and business transfers.
  www.newcome.de
- **Runner-up:** JA-YE, an independent Norwegian NGO that works with universities and national tax authorities to help students operate real companies.
  www.ue.no

ENTERPRISE SUPPORT AWARD

- **Winner:** Lienz Marketing Department, Austria, for successfully encouraging local inhabitants and businesses to work together on decisions affecting the town's future.
  www.stadt-lienz.at
- **Runner-up:** The Welland SSP Ltd, UK, a not-for-profit company established in 2002 to tackle rural depopulation by developing local innovation centres, training networks and links to other networks.
  www.thewellandssp.co.uk

RED TAPE REDUCTION AWARD

- **Winner:** Chamber of Commerce and Industry, Centro Region, Portugal with its new system making it possible to set up a commercial company within one hour in a single administrative office.
  www.cec.org.pt
- **Runner-up:** The city of Chomutov, Czech Republic, centralised its services for entrepreneurs in 2003. It can now provide information for the self-employed on issues as varied as trade certificates and building permits.
  www.chomutov-mesto.cz

INVESTMENT IN PEOPLE AWARD

- **Winner:** The Fondation pour la Recherche et l'Enseignement de l'Esprit d'Entreprendre (FREE) helps to develop a spirit of entrepreneurship among Belgium's French-speaking population and to increase the number of companies created in Wallonia.
  www.freefondation.be
- **Runner-up:** The Ida-Viru Enterprise Centre, Estonia, helps the unemployed to start their own businesses. Its efforts have led to the creation of some 60 companies ranging from private messenger services to ostrich farming.
  www.ivek.ee

RESPONSIBLE ENTREPRENEURSHIP AWARD

- **Winner:** Autopromozione Sociale, Rome, Italy, has provided support to over 750 start-up companies since it was established by the municipality of Rome in 2004 and has ensured that their activities are in harmony with the local social and physical environment.
  www.autopromozionesociale.it
- **Runner-up:** The Business Centre of Nova Zagora, Bulgaria, which helps to develop entrepreneurial skills among disadvantaged young people, especially those from ethnic minority backgrounds.
  www.bcnzagora.org

SPECIAL MENTIONS

The jury also highlighted the following two projects: The Slovak municipality of Slovensky Grob, which has boosted tourism by reviving its traditional dish of roasted goose, and Rock City AB, Hultsfred, Sweden, which supports creative entrepreneurship in music, media and tourism.
www.slovensky-grob.sk and www.rockcity.se

are devising to tackle common problems of skills shortages, rural depopulation and declining industrial areas.

Some are very much top down, others bottom up. Some are public initiatives, others are public–private partnerships. What they all have in common is the enthusiastic participation of the local community.

From a total of over 400 entries, 51 national nominees went forward to European level for review by an independent jury with representatives from the worlds of business and academia. This whittled the entries down to 13 finalists for the six categories, before going on to choose the winners. Each project was judged against the following criteria: originality and feasibility, impact upon the local economy, improvement in local stakeholder relations, and transferability to other regions across Europe.

Looking ahead

The Commission is encouraging the winners and the nominees to share their experiences as widely as possible with others and is currently investigating suitable opportunities outside Brussels to enable them to do this.

The exercise is not limited to the finalists. It is expected to include, for instance, a Hungarian project which uses electronic cards to enable SMEs to cover small loans for their day-to-day activities. Although not short-listed, the scheme offers a practical solution to the cash-flow problems and access-to-finance obstacles that many firms face.

A short video is also available, featuring practical information about the awards. It tells the stories behind three of the successful projects, demonstrating how they turned the germ of an idea into reality.

At the end of January, officials from the Directorate-General for Enterprise and Industry met their contact points in member states to assess the lessons to be learnt from these first awards and decide if any refinements need to be made before launching the second series. This will be judged during the second half of the year when Portugal, which has enthusiastically supported the initiative, will hold the rotating EU presidency.

TINA ZOURNATZI

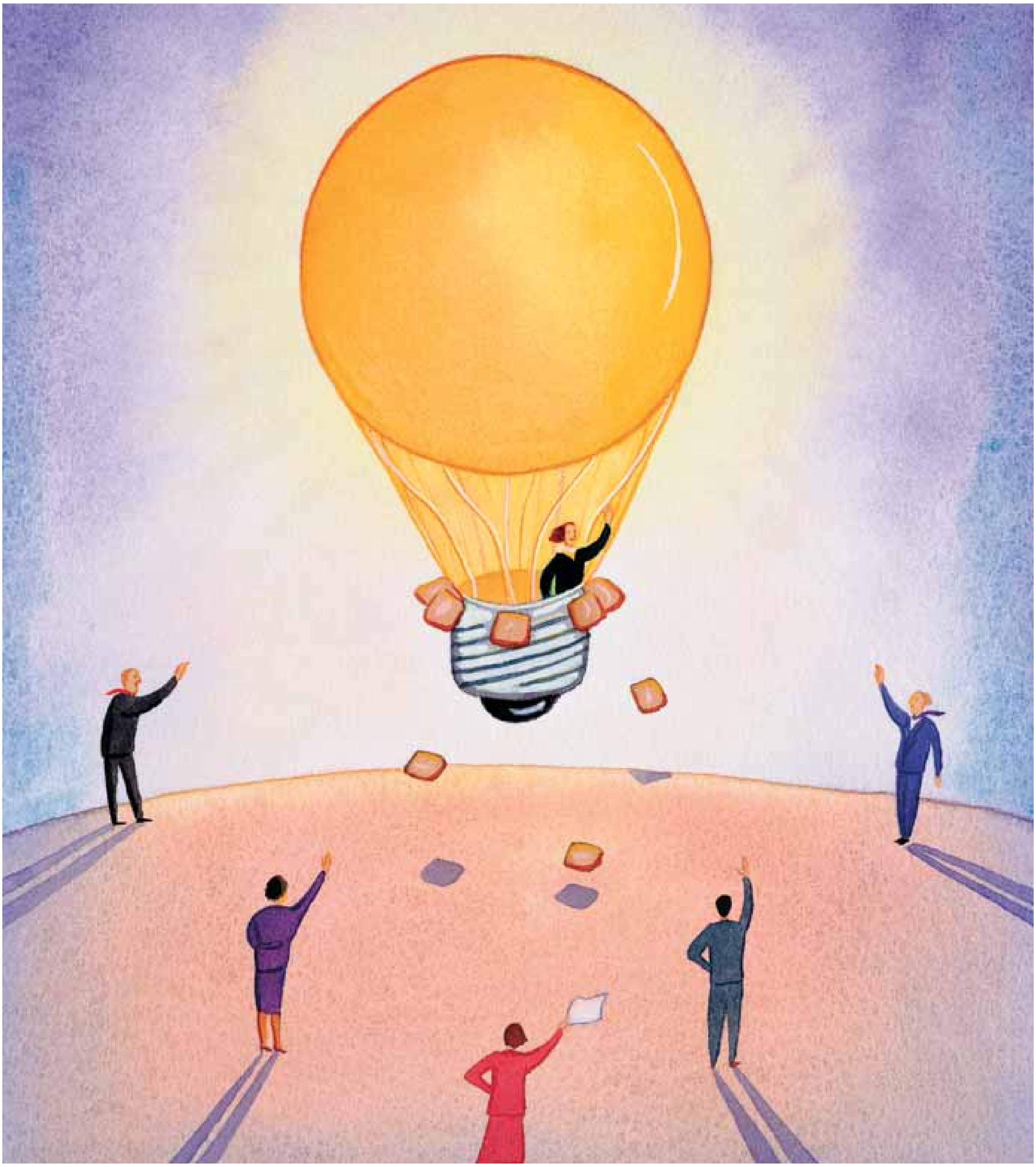
entr-horizontal-aspect-sme-policy@ec.europa.eu

For useful links, visit the online version of the article at

ec.europa.eu/enterprise/library/ee_online/art22_en.htm

COMPETITIVENESS

Delivering Better Regulation



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The European Commission has recently carried out a strategic review of the Better Regulation initiative it presented in February 2005. This analyses the progress made in ensuring a high-quality regulatory environment and proposes concrete and measurable ways to meet the main challenges ahead. To give further impetus to the process, EU leaders are being asked to agree at their next European summit in March to aim for a 25% reduction in administrative burdens by 2012.

The Commission's Better Regulation programme is entering a new phase as the principles announced almost two years ago are put into practice throughout the institution and new targets are set.

As Günter Verheugen, the Commission Vice-President responsible for Enterprise and Industry, said towards the end of last year: "We are moving ahead with an unprecedented drive to cut administrative burdens in Europe. We have been speaking about this for some time, now we are delivering. This will make a real difference to European businessmen."

The programme's goals remain the same: to establish a process that will ensure that regulations are only used when other options are not appropriate and to ensure that the burdens they impose on businesses are proportionate to their aims. As such, Better Regulation is a centrepiece of the Commission's wider growth and jobs package designed to enhance the Union's competitiveness, economic growth and employment performance.

It is also leading to the development of a new political culture within the Commission, which traditionally has tended to turn to legislation to implement European policy. Now, the emphasis is very much on extensive consultation with outside interests and careful assessment of the impact of regulatory measures before going down the legislative route.

As with any major initiative, practical implementation can be slow and tends to attract less media attention than high-profile announcements. But significant progress is being made. The Commission is allocating resources and €20 million to ensure the programme is followed through and features as a key pillar of its annual work programme.

As President Barroso told MEPs at the end of last year: "We have responded to calls from the Parliament to include a list of simplification measures and withdrawals of legislative proposals in the work programme. This underlines the message that Better Regulation is now an integral part of the Commission's day-to-day tasks."

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Impact Assessment Board

The Commission will establish an independent board to examine whether the assessments carried out on the economic, social and environmental impacts of future legislation are sufficiently rigorous. Such studies are now a regular feature of the institution's work for all major legislative and policy proposals. Since 2003, over 160 have been completed and since last autumn, summaries of the reports exist in all official EU languages.

The exercise routinely examines options ranging from no EU action to legislation. The process has led to significant changes in some planned measures. For instance, impact assessments on biomass, the urban environment and copyright in the online music sector led to the conclusion that legally binding measures were not necessary.

In future, the five members of the new Impact Assessment Board will police the process by carrying out quality controls. They will act independently of the policy-making departments and report directly to President Barroso. Initially, the board will examine draft final assessments, but will gradually become more closely involved earlier in the process, offering advice on the approach and methodology to be followed.

In parallel, the Commission launched an external evaluation of its impact assessment procedures last August, the results of which are expected to be published in February. It is also preparing an action plan to improve the way it evaluates the consequences of existing legislation and activities.

Cutting red tape

Some costs on businesses of implementing legislation are unavoidable. Complying with the need to install safety equipment is a case in point. But some purely administrative costs, such as the legal obligation to meet different reporting requirements, can be avoided. It is these the Commission wants to reduce wherever possible.

Administrative costs vary from country to country. According to one study, these can amount to 1.5% in the UK, Finland and Sweden, but be as high as 4.6% in Austria, Spain, Portugal and Slovakia and even 6.8% in Greece. The Commission, which has developed its own methodology in this area, estimates that a 25% reduction in administrative costs from national and European legislation could yield up to 1.5% of GDP – the equivalent of €150 billion.

That 25% target by 2012 is one that the Commission would like Member States to endorse at their March European summit, in what is very much a top-down process. And while the principle of Better Regulation itself is somewhat wide, reducing administrative costs is highly focused. It is also an exercise which reverses the burden of proof, requiring regulators to justify why the administrative burdens of the measures they propose, despite the costs involved, are necessary.

The Commission is already working on ways to measure the burden on businesses of existing legislation and chart progress towards the final target. This involves ensuring different forms of measurement are compatible and identifying whether specific responsibilities placed on companies are local, national or European in nature. Research indicates that around two-thirds of the costs involved originate at national level.

In January 2007, the Commission presented an action plan for administrative cost measurement and reduction of administrative burdens. This contained some initiatives that can be taken immediately and a coordinated longer-term strategy for both EU institutions and national authorities. This will later be supported with clear milestones that can be measured against firm data, to monitor progress towards its ultimate target.

Simplifying and screening

Simplifying the stock of existing European legislation is a central feature of the Better Regulation programme. Around half of the 100 proposals which were originally selected for this treatment by 2008 had been adopted by the end of 2006. These range from simplified procedures for payment services to measures to stimulate the recycling market.

Further initiatives have now been identified in agriculture, fisheries, labelling and statistics. These will make it easier, for instance, to stimulate textile innovation by speeding up adoption of new fibre names and to improve toy safety by updating safety requirements.

Codification is another technique to inject order into an original law and the subsequent amendments which may have been made over many years by bringing the various texts into one. Some 500 acts, which would replace 2,000 pieces of existing legislation, have been identified, of which 52 are already on the statute book and 33 are being examined by EU governments and the European Parliament.

The current Commission is also recommending that its successors should screen any pending proposals within six months of taking office to determine whether they are still in line with the political priorities of the day. The Barroso Commission led the way in 2005, slating for withdrawal 68 proposals which were not considered to match its economic growth and jobs strategy.

Joint effort

The Commission may have launched the Better Regulation programme, but it cannot make a success of it on its own. Input from other EU institutions and national authorities is also essential. As the strategic review makes clear, proposals to simplify legislation cannot take effect until approved by EU governments and MEPs. Similarly, to be fully effective, the principles applied by the Commission itself need to be more widely implemented and national moves to gold plate European law by adding extra requirements discouraged.

Both the Parliament and the Council are now committed to better lawmaking through an inter-institutional agreement and are taking steps to apply this in practice. Almost 20 Member States have drawn up a Better Regulation strategy and 17 are in the process of measuring administrative costs. Several have set targets for reducing them and impact assessments are on the increase.

The range of Better Regulation activities now underway is an eloquent rebuttal of critics who equate it with deregulation and warn that Europe's social and environmental standards will suffer. On the contrary, they demonstrate that the concept is not about undermining achievements, but about achieving more with less.

GERT-JAN KOOPMAN

entr-impact-assessment@ec.europa.eu

For useful links, visit the online version of the article at

ec.europa.eu/enterprise/library/ee_online/art23_en.htm

COMPETITIVENESS

Investigating European performance

Economic growth and job creation are at the heart of the EU's current priorities. But what factors determine the productivity that influences Europe's overall competitiveness levels and ability to deliver these two principal objectives? Some of the answers are to be found in the European Commission's latest competitiveness report.* Now in its tenth year, the report does not offer policy prescriptions. Instead, it provides decision makers, through economic theory and empirical research, with a better insight into the microeconomic influences at play.

The new edition has been redesigned to ensure a closer link with the microeconomic aspects of the Union's economic reform agenda. In this regard, it focuses on three of the four priority actions identified by EU leaders in March 2006: knowledge and innovation, unlocking business potential and the development of an efficient and integrated energy policy.

Key policy challenges

The Commission attaches high importance to the liberalisation of energy markets since the introduction of competition can lead to greater cost-efficiency and a fall in prices for consumers. While there is no doubt that liberalisation in this area has been set in motion and is ongoing, benefits to consumers have so far been limited due to limited competition, as incumbents maintain a strong grip on production, imports and infrastructures.

In the second priority area – ensuring a healthy business environment – research shows that regulation can have an impact on economic growth, productivity and employment. For instance, it is estimated that the Commission's target of reducing red tape by 25% would raise GDP per capita by 1.5% – a significant increase compared to other structural reforms. The impact would be even greater in countries such as Greece, Italy, Poland, Spain and the Czech Republic, which have a more restrictive regulatory environment.

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The report suggests that progress has already been made across the EU and that all Member States are taking action regarding Better Regulation and the business environment in general. Work on measuring administrative costs and setting targets for their reduction is under way in most Member States and the same applies for setting up Impact Assessment systems.

** European Competitiveness Report 2006 SEC(2006)1467 and companion Commission Communication COM(2006)697 final.*

However, real challenges remain, in particular for the Member States in a less positive starting position. The general process of Better Regulation is still in its early stages and its ultimate success will be influenced by many factors that cannot easily be accounted for. The earnestness with which existing proposals are implemented will also play an important role, as will possible resource constraints.

Innovation is the lifeblood of competitiveness and governments are using a variety of grants and tax incentives to nurture the process. Given the degree of experimentation taking place, the report makes clear there is wide scope for exchange of best practice. This would be more easily achieved if evaluations of existing measures were more frequent, systematic and comparable.

However, gaps still exist and must be addressed. In particular, there is a need to develop cross-border venture capital and debt financing of innovative projects and to provide early-stage risk capital.

Examining the current debate on the lead market approach, the report concludes that there is little empirical evidence to suggest that policies deliberately aiming to create such markets for champion products and technologies are necessarily effective.

Instead, it suggests that innovation and technology policies should incorporate those factors that could contribute to a successful lead market strategy. These include taking account of global trends and conditions in non-EU markets, lowering production costs and allowing competition between different innovation designs.

Manufacturing sectors

The report paints a detailed picture of two fast-growing, high-technology sectors – the ICT industry and pharmaceuticals.

Europe has many strengths in ICT. It produces top quality goods and is particularly strong in knowledge-intensive production and design, software development and telecommunication services.

However, on the negative side, it is experiencing a huge manufacturing trade deficit (€55 billion in 2004), is vulnerable to relocation to South East Asia and has a lower R&D density than either the US or Japan.

To improve the sector's competitive advantage, there is a need for companies to increase R&D investment and for horizontal policies that will foster innovation, entrepreneurship and e-skills and will protect intellectual property rights.

A similar picture is emerging in pharmaceuticals. The European pharmaceutical sector is growing in terms of both production and employment, and its share of global exports is increasing. This good performance is due partially to a delocalisation of US production to Europe, but also to an increase in its cost competitiveness.

Nevertheless, the overall picture gives rise to concern because of the considerable gap that the European pharmaceutical industry has, vis-à-vis the US, in labour productivity and in innovation performance. Stronger competition in the US market and the effects of policies to contain health costs in Europe explain to a certain extent the different industry dynamics. The report emphasises the importance to the competitiveness of the European pharmaceutical industry of striking a careful balance between the provision of new medicines at affordable prices and an environment that provides suitable rewards for innovating companies – a challenge the EU's Pharmaceutical Forum is addressing.

GEORGE LEMONIDIS

entr-compet-economic-reforms@ec.europa.eu

For useful links, visit the online version of the article at

ec.europa.eu/enterprise/library/ee_online/art21_en.htm

COMPETITIVENESS

Looking to the long term in energy strategy

A change in energy trends is inevitable as increasing pressure is placed on traditional sources and a successful strategy against climate change becomes more imperative. The challenge is to effect the change without damaging the competitiveness of European industry. The high-level group on competitiveness, energy and the environment, in its second report, examines how this could be achieved.

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The high-level group (HLG) sets out three benchmarks against which energy-related proposals should be measured. They must be sustainable, secure and competitive, not placing European firms, which have to bear increasing responsibility for reducing carbon emissions, at a disadvantage compared to their international rivals.

The group has taken a long-term perspective, stretching from 2030 to 2050. This is the timeframe that investors will need to consider when taking major financial decisions in the energy sector and energy-intensive industries.

Unlike the past, when energy utilities tended to be publicly owned and investment came from the state, the responsibility now falls largely on the private sector. If it is to shoulder that burden, it will need suitable sources of finance, a predictable regulatory framework and an overall climate that nurtures long-term investor confidence.

To achieve this, the HLG points to a range of possible measures: regulations, general targets and market-based mechanisms such as the emissions trading scheme. This, it says, could be extended to appropriate sectors and over time become the main market-based incentive for investment in mature low-carbon technologies.

While the EU has taken the lead in tackling climate change, and will continue to do so, it is looking to encourage other countries to introduce similar measures to address what is a global, not national or regional, problem. Such international cooperation will increase the overall effectiveness of the different initiatives and ensure that European industry is not alone in playing its part.

Potential measures

The HLG recommends the creation of a strategic European Energy Technology Programme. Funded from EU, national and industry sources, it would aim to accelerate technology development and deployment and give European firms a lead in the field which, after satisfying domestic needs, they could use as a base for export markets.

The trend can already be seen with wind power technology. Largely developed at the outset in Denmark and Germany, firms are now satisfying strong demand for their products in the United States. Similarly, if European companies can develop carbon capture and storage, they could find a booming market in the future in China with its many coal-fired power stations.

The report emphasises the need for industry to be aware of the important benefits of energy efficiency technologies, in terms of both financial savings and reducing CO_2 emissions.

As companies consider investment strategies that could have consequences for two decades or more, appropriate risk-bearing tools, including a clear understanding between lenders and borrowers, to support these financial decisions will need to be in place.

The HLG recommends that the Commission consider cooperating with the European Investment Bank to create a funding scheme that would support new risk and revenue-sharing projects. Its aim would be to bridge the gap between existing financial lending and the additional investment costs involved in setting ambitious and accelerated timetables for deploying new technologies.

Financial institutions could be encouraged to support energy-saving investment projects and to tailor energy efficiency packages for SMEs. The group raises the possibility of modified tax schemes that favour investments in innovation, energy efficiency and energy conservation.

Targeting the future

The HLG recommends that the EU set a realistic, unilateral, long-term target for the reduction of CO_2 emissions which would replace a myriad of existing sub-targets, where appropriate. Such a target, set at an aggregated level should be considered in the international context and be consistent with the Lisbon Strategy for growth and jobs.

This target would be broken down into cost-effective, operational, intermediate targets so as to ensure that Member States have the flexibility over the low-carbon technology options available and that energy mix choices remain a national remit. It would also reduce uncertainty and provide guidance to investors, while minimising market distortions and avoiding favouring specific technologies.

The contents of the group's second report will now feed into the Commission's work programme, especially the energy package which it is looking to present in January and the ongoing interdepartmental work on sustainable coal.

The HLG will now turn its attention to technology perspectives and innovation in energy intensive industries and the impact of environmentally harmful subsidies.

STEPHEN PATHIRANA, JULIO CARDOSO

entr-competitiveness-sustainable-dev@ec.europa.eu

For useful links, visit the online version of the article at

ec.europa.eu/enterprise/library/ee_online/art20_en.htm

SINGLE MARKET

Extending standardisation benefits to SMEs

Standardisation is one of the pillars of the European Union's single market. It enables manufactured goods, once they have met agreed standards, to be sold across the continent without having to satisfy other formalities. For various reasons, small and medium-sized enterprises are not sufficiently involved in the process. Nor do they reap the full benefits. The Commission believes it is now time to correct these deficiencies and develop a new partnership between standards organisations and SMEs.

Almost 20,000 voluntary standards underpin the free movement of goods throughout Europe and new European standards are developed whenever there is demand for them. Their presence oils the wheels of the EU's economy by removing national barriers and helping to develop the Union's competitiveness.

The benefits for large companies used to trading across borders are clear to see. For SMEs active in standardisation, their participation in developing standards is also a strategic asset, and examples may be drawn from diverse areas such as personal protective equipment or telecommunications. Standardisation helps these firms to be market leaders at home and abroad.

However, the benefits are less obvious for smaller firms not so directly involved with standards. Too often, SMEs are unaware of the standards that apply to their products and services and have difficulty keeping track of new ones. For them, standards either have little relevance or are another layer of complex bureaucracy. They mean costs, not a route towards greater competitiveness.

The Union is already helping small businesses to benefit from standardisation. It supports NORMAPME, the European Office of Crafts, Trades and Small and Medium-sized Enterprises for Standardisation, to represent the interests of SMEs at European standardisation committees. The EU also provides SMEs with information on standards through its Euro Info Centre network.

But the message from the World Standards Day conference in mid-October was that more needs to be done to help SMEs extract the maximum advantage

from standardisation. To achieve this, standards must be easier to use and SMEs must be better represented in the drafting process.

SME involvement

The Commission would like to see more attention paid to the constraints under which SMEs operate.

Few have the time, money or resources to be regularly involved in the work of the European standardisation bodies: CEN, CENELEC and ETSI.*

To overcome these hurdles will require input from many quarters. Procedures need to be more friendly for small businesses, SME organisations should be readier to invest the time and resources needed to reap the benefits that standards can deliver, and practical help should be made available to allow them to participate more. Standards could also be accompanied by simplified guidelines on their usage.

National authorities have an important role to play in achieving this goal, as is demonstrated by the findings of the Commission-financed study, 'SMEs and Standardisation in Europe', presented to the October conference.

The authors examined the national measures in place in 32 European countries to encourage SME involvement in the standardisation process. They found that some – Belgium, Estonia and Greece – had none. Others – Cyprus, Malta and Lithuania – had a small number. A handful had introduced a score or more of initiatives: Finland (46), France (42), Italy (28) and Germany and Hungary (25 each).

The support ranges from travel allowances, meetings and newsletters to the provision of standards at reduced rates and special training programmes. The report selected 23 of the 400 or so measures it identified and offers these as examples of good practice. These include 13 initiatives from national standards bodies, six from craft and SME organisations and four from national administrations.

Now that the political priority has been agreed, the Commission will monitor the moves taken to make the commitment a reality and will continue to offer support to increase SME involvement in the process.

JAVIER ARREGUI ALVAREZ

entr-standardisation@ec.europa.eu

For useful links, visit the online version of the article at

ec.europa.eu/enterprise/library/ee_online/art19_en.htm

* *The European Committee for Standardisation, The European Committee for Electrotechnical Standardisation and The European Telecommunications Standards Institute.*

SECTORS

Pharmaceuticals: getting the chemistry right

Reconciling the different needs of patients, pharmaceutical companies and public health services is far from easy. The first require quality treatment. The second need an environment in which investment and innovation are rewarded, and the third are constantly struggling to keep costs down. The Pharmaceutical Forum set up by the Commission under the joint chairmanship of Vice-President Verheugen and Commissioner Kyprianou has just produced its first progress report setting out a framework for future work in these three key areas.

© Gettyimages

Once the world leader, Europe's pharmaceutical companies are losing ground to their competitors. Two simple statistics illustrate the challenge the industry is facing. Over the past 15 years, investment in developing new drugs in the United States grew 4.6 times. In Europe, the figure was 2.8. In 2004, two-thirds of the world's 30 top selling medicines were developed in the US. Increasingly, competition is arriving from elsewhere in the world: especially from China, India and Singapore.

Despite losing its premier position, the European-based pharmaceutical industry is making a major contribution to the creation of jobs and economic growth in Europe, to its trade balance and to the development of the continent's science base.

At the same time, public health services are coming under greater financial strain as patient demands increase, new medicines and technologies become increasingly expensive, and people live longer.

Although the primary responsibility for policy in these sensitive areas lies with national governments, there are areas where the EU has a role, especially as all are struggling with the same problems. In response, the Commission created the Pharmaceutical Forum, where experience could be shared, the benefits of

Europe-wide cooperation explored, and concrete recommendations for progress could be developed.

The Forum builds on the earlier work of the G10 Medicines process that was launched in 2001. Among other things, this emphasised the important role the pharmaceutical industry could play in meeting European society's health goals.

But the Forum is a far more ambitious exercise. It has a wider range of participants: Commissioners, MEPs, government ministers and senior officials, and representatives from industry and public health and patient groups. It is also tackling three core issues: pricing and reimbursement policy, information to patients and assessment of the relative effectiveness of medicines. Its first progress report sets out issues that individual working groups will address in more detail in the coming months.

Pricing and reimbursement

This is arguably the most difficult issue of the three. A balance needs to be struck between the legitimate need to keep health authorities' costs down and recognition that industry looks for appropriate rewards for investing heavily in developing new drugs.

The two can come together by ensuring the provision of optimal service to patients through intelligent, not increased, expenditure. By focusing on a sustainable long-term approach, innovative developments that may appear expensive in the short term might over time prove more economical.

With 27 different national systems for the reimbursement of medicines, there is an inevitable downward pressure on prices. If this is taken too far, however, it could act as a disincentive for pharmaceutical companies, persuading them to move their R&D activities to the US or the Far East. What is at stake is not so much whether Europe will have access to innovative medicines – they can always be imported – but whether they are developed here.

Within its overall aim of trying to make the system function more effectively and for decisions to be taken as fast as possible, the Forum has identified a number of main areas.

Firstly, given the wide diversity in pricing, reimbursement and cost containment policies around Europe, experiences at national level will be shared as much as possible so that the most effective practices can be identified.

Secondly, for regulatory or budgetary reasons or because of administrative delays in bringing authorised drugs to the market, patients throughout Europe have unequal access to medicines. The working group is being asked to identify ways of eradicating these inequalities so that the necessary treatment may be available to anyone in need as early as possible.

Thirdly, the working group will examine trade and distribution procedures in the pharmaceutical industry, while the fourth area involves responding to calls by Member States to find ways to improve data exchange when pricing decisions are taken.

Lastly, pharmaceutical advances should bring their own rewards, and a task force is being established to define the value of innovation. The remit is far from easy since genuine breakthroughs are rare and most new drugs tend to be incremental improvements of existing ones.

Information to patients

Understandably, individuals are demanding more and more information about the medicines available to treat their various illnesses. The growth of the internet means that there is no shortage of data – at least for those who understand English and can operate a computer.

However, anyone who does not meet these criteria is poorly served, and even those that do cannot always be certain of the authenticity and reliability of the web sites they access.

The Commission's starting point in this debate is clear. Patients and consumers should have access to factual information. Informed patients make better use of medicines and can save health services money. Information should be provided at the national or regional level where local traditions and care systems can be factored in.

The extent to which industry has a role here is a matter of considerable debate. Can a clear dividing line be drawn between factual, non-promotional information and advertising? If this can be agreed, how should it be implemented? On a self-regulatory basis by industry itself, or by a stricter system which monitors behaviour and has penalties for any abuse?

Günter Verheugen, the Enterprise and Industry Commissioner, would like to see industry have the right to produce non-promotional information about their medicines. This would comply with strictly defined rules and would be subject to an effective system of control and quality assurance.

The Commission Vice-President has confirmed that this year he will present a new framework for information to patients on medicines. This will update the present legal arrangements, which were agreed in the early 1990s, to take account of today's realities, not least the internet.

Relative effectiveness of medicines

Relative effectiveness systems are being developed by Member States, often as a way to contain public health costs on national exchequers, while still allowing companies a fair reward for their innovative efforts. As a tool, they can be used to help decide which medicines can provide specific added value to patients.

To optimise their impact and to prevent unnecessary duplication, the Forum is proposing that different national experiences in assessing medicinal products should be pooled. Specifically, the working group will consider ways to improve the quality and quantity of the data required to carry out cost-effectiveness and relative efficacy assessments.

The way ahead

The Pharmaceutical Forum, which held its first session at the end of September 2006, will meet again in 2007 and 2008. This year, it is expected to concentrate on information to patients and relative effectiveness systems, before considering pricing and reimbursement next year.

JAMES COPPING

entr-biotechnology@ec.europa.eu

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ec.europa.eu/enterprise/library/ee_online/art17_en.htm

GLOBAL MARKETPLACE

Competing in the world

Never before has the European Commission seen the Union's trade strategy towards its international partners dovetail so closely with its internal economic and political priorities. In the past, there was a tendency to separate domestic and foreign policy. They were two different arenas with few mutual points of contact. In today's globalised world, that distinction is no longer valid. Each influences the other.

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This interaction is at the heart of the Commission's new blueprint for the Union's relationships with its major trading partners, 'Global Europe, Competing in the World'. The communication's subtitle, 'A Contribution to the EU's Growth and Jobs Strategy', makes clear that trade policy is now an integral element – the external dimension – of the Barroso Commission's overriding objective of strengthening Europe's economy and boosting employment. As such, this imperative of developing the Union's competitive capacity will define its trade strategy for many years to come.

The competitiveness of Europe's businesses depends on three related factors: the EU's own internal policies, its openness to international trade and the domestic and foreign policies pursued by its major trading partners.

The first two are largely within the Union's own control, but the third depends on its ability to convince others of the mutual benefits of an open trading system. Almost two decades ago, the Commission began the process of creating a large internal market within Europe's borders by gradually eliminating national barriers. Consumers and companies have both gained as a result.

Now, the Commission is looking to use that unique experience as leverage to remove obstacles preventing European companies from developing new markets in the rest of the world. The EU's regulatory procedures and high-quality rules can be examples to be emulated on a wider scale.

The Union intends to play a leading role in sharing this best practice and in improving the compatibility between its regulations and those of its main trading partners. This cooperation can bring clear benefits for all concerned and reduce unnecessary costs for businesses having to comply with different rules.

It is not just European manufacturing that will benefit from this more robust trade policy. So too will service industries. Ranging from finance and telecommunications to transport and construction, they are among the most competitive in the world. But in many regions, they face obstacles that freeze them out of local markets. Host countries will also gain. An efficient service sector can help modernise infrastructure and create an environment conducive to foreign investment.

The change in global supply chains and the practice of outsourcing different company functions have fundamentally altered the way businesses operate. This has implications for global economic relations and is a strong reason for reshaping the EU's trade policies to take account of current realities.

Fair treatment

At the core of the Commission's approach is the belief that rejection of protectionism at home must be accompanied by active European efforts to open up markets and create fair conditions for trade abroad.

Tackling barriers to trade, investment and business activity around the world plays a key role in improving

the competitive position of European companies. This increasingly takes account of the whole operating environment surrounding EU firms in third markets and places greater emphasis on non-transparent and discriminatory regulatory obstacles.

The policy is largely targeted, not at the world's least developed nations, but at the major emerging countries and regions that benefit from the global trading system and are able to hold their own with international competition. Already, this middle-income group represents a growing share of the Union's external trade.

One priority is access to third country markets. Previously, unfair barriers used to take the form of visible customs duties. Now they consist of more subtle non-tariff obstacles. They range from excessively stringent sanitary and phytosanitary requirements to a variety of conformity assessment procedures for the same product. They are all designed to protect domestic producers.

The Commission fully supports the need to regulate trade in products and services to ensure high human health and environmental standards. But the conditions attached should be transparent, non-discriminatory, justified and proportionate to the ultimate objective.

Reciprocity is a key principle. The EU is now one of the world's most open markets from which foreign companies also benefit. But too frequently, it is a one-way street. The markets of some of the Union's main trading partners almost appear to have 'No Entry' signs at their borders. In some cases, these economies combine high growth with staunch defences against EU exports.

Addressing non-tariff barriers is complicated, takes time and is not fully covered by World Trade Organisation (WTO) rules and procedures. But a combination of international standardisation and regulatory dialogues can provide the passport to ensure that European products may legitimately enter other markets without unnecessary red tape.

It is not just the ability to enter foreign markets that is important; so too is access to energy and raw materials. There is increasing international competition for these precious commodities. The Commission is drawing attention to the need to ensure that other parts of the world do not use unnecessarily restrictive measures to shut out European companies from their supplies.

Other priorities

Investment in creativity, research, design and quality are major assets of the EU economy. But being able to access foreign markets is of little value for innovative companies if their intellectual property rights are not protected and enforced.

Sadly, that is the case in some parts of the world. The rights may exist on paper, but not in practice. The existence of counterfeit copies of their genuine products not only robs companies of legitimate revenue from their investments, but can damage their reputation and put their very viability at stake.

The EU's trade policy will now attach a higher priority to stamping out these abuses. The Union is not acting alone. In June 2006, it agreed a joint action plan with the US to protect intellectual property rights. It is also cooperating closely with Japan.

Public procurement is increasingly on the EU's trade agenda. It is an area of significant untapped potential in both advanced and emerging economies for European exporters, but one from which they are excluded by national regulatory barriers. It is now the single largest trade sector not covered by multilateral rules, accounting for between 10 and 25% of the GDP of the Union's partners.

While EU public procurement rules enable companies in other countries to tender for Union contracts, subject to certain WTO conditions, the same is not always true in return. The Commission is looking to end that imbalance.

Competition policy can also influence trade. As the Commission reviews the EU's own rules, particularly on state aids, it will bear in mind the impact these have on domestic companies' external competitiveness. It is also looking to develop international rules and global cooperation to ensure that European enterprises do not suffer in third countries from anti-competitive practices such as unreasonable subsidies for local firms.

As a last resort, the Union uses trade defence instruments, notably anti-dumping duties, to protect companies from unfair competition from abroad. However, the world in which they are now deployed is very different from the one in which they were devised. The Commission is preparing a consultative green paper to determine if they need to be modified to best serve the Union's interests in an increasingly complex global market.

The Commission will continue to act against unfair practices such as anti-competitive pricing, subsidies or other state induced distortions. It will also use the remedies offered by the WTO to challenge practices by its trading partners which it considers are incompatible with multilateral rules.

China

The Commission has identified China as the single most important challenge for EU trade policy. The country is now the EU's biggest source of manufactured goods and Europe's fastest growing export market.
The EU has a well-developed regulatory dialogue with Beijing and the two partners work together towards the convergence of their respective technical rules (standards, technical regulation and conformity assessments). The EU–China relationship is also bolstered by an industrial policy dialogue in which key strategic issues, such as increasing pressure on the steel industry or Chinese automobile industry policy, can be examined.
Now, the Commission is requesting that China fulfil its WTO obligations, open its market and trade fairly. In particular, it is pressing for tougher action to protect intellectual property rights and will help European businesses by providing practical help on the ground.

Trade agreements

The Commission firmly believes that the Doha Development Round of trade negotiations is the best vehicle for meeting its many objectives and for ensuring that the benefits of liberalisation are fairly distributed around the globe. But, at the moment, its fate is far from certain.

Whatever the future holds for the talks, cross-border business will continue to develop and an effective trade policy must respond to new challenges. As a result, the Commission is looking to negotiate free trade agreements with key partners. It is not alone in this. The US is considering 14 such agreements. With care, these can be stepping stones, not stumbling blocks, to wider multilateral agreements.

Free trade agreements are not new. Whereas in the past, they were largely motivated by political or development reasons, now the EU's main criterion is increasingly economic. The key criteria which will be applied will be the market potential offered by prospective partners, the degree of protection they apply against European exports and the extent to which they are negotiating similar agreements with the EU's competitors.

Using these criteria, the Commission has singled out Korea and the ASEAN and Mercosur countries as immediate priorities. They are likely to be followed by India, Russia and the Gulf Cooperation Council.

As for the transatlantic relationship – the Union's most important commercial partnership – the Commission recognises the need to inject further momentum into current efforts towards the creation of a barrier-free marketplace.

Looking ahead

Confirmation that trade and enterprise policy are increasingly intertwined can be seen from the fact that the Commission's paper is being examined both by national trade experts and by ministers whose brief includes policies to improve Europe's competitiveness.

EU governments have already made clear that they share the Commission's analysis that initiatives to foster the Union's competitiveness must cover both internal and external measures working in tandem and that trade policy is an essential ingredient in the push for economic growth and job creation.

The Commission is currently working on more detailed proposals in each of the areas it has identified. The consultative green paper on trade defence instruments was adopted on 6 December 2006 and other initiatives will follow.

Germany has made the link between trade and competitiveness one of the priorities of its six-month EU presidency beginning in January, and the theme will feature prominently at the EU leaders' Brussels spring summit in 2007.

VÉRONIQUE HYEULLE

entr-international-aspects@ec.europa.eu

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ec.europa.eu/enterprise/library/ee_online/art18_en.htm

MOREOVER

Helping the smallest become more competitive

For the first time in a decade, the European Commission is organising a major conference dedicated entirely to craft and small enterprises. The two-day event will take place in Stuttgart, Germany, on 16 and 17 April 2007.

Since the last conference in Milan in 1997, the dynamics of globalisation, EU enlargement, demographic change and technological developments have had a fundamental impact on the business environment in which these companies operate and, as a result, on the overall European economy. It is now time for an in-depth assessment of ways in which the EU can continue to help the sector.

'Challenges and opportunities for craft and small enterprises in the European Single Market' is the title of this fourth European conference focusing on these businesses. It provides an opportunity to take stock of the wide spectrum of the craft sector's economic, social and cultural strengths, to present concrete examples of successful practices and to consider policy responses.

Over 1000 participants are expected at the event, which will concentrate on three crucial topics: skills for the future, developing new markets and improving the business environment. Its importance is underlined by the presence of Chancellor Angela Merkel, President of the Council of the European Union, Günter Verheugen, European Commission Vice-President and Enterprise and Industry Commissioner, Michael Glos, German Minister for Economics and Technology and Günther H. Oettinger, Prime Minister of Baden-Württemberg.

For further details and registration:
ec.europa.eu/enterprise/entrepreneurship/craft/4th_conference.htm

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NB-BH-06-024-EN-C