BIS | Department for Business Innovation & Skills

LET'S GET DOWN TO BUSINESS

Smart regulation, more growth, better Europe

NOVEMBER 2011

Foreword

by Mark Prisk MP, Minister of State for Business and Enterprise

How can the Government ensure that the EU regulatory framework offers the best growth opportunities for UK businesses?

This is the question posed as part of this review with Balfour Beatty, GlaxoSmithKline, Kingfisher and Tribeka Limited.

Illustrated by 16 specific case studies, the answer is clearly set out in this report:

We must continue our efforts to reduce the overall EU regulatory burden; ensure EU regulation fosters, rather than stifles innovation; get the internal market to realise its full growth potential; and end any UK gold-plating of EU regulations.

These aims will continue to be the cornerstone of the Government's EU growth strategy. We will use the 16 specific case studies as well as evidence from business groups and the Red Tape Challenge, to get down to the business of energetically working with the European Commission, the European Parliament and other Member States to make these aims a reality for both UK and EU businesses.

Business Views

"Over-complex and burdensome regulation will always act as a block on growth. The combined efforts of member states to find solutions to the economic challenges we all face will be given significant impetus as a result of this very welcome drive to foster simplicity, logic and clarity across the regulatory framework."

Chris Vaughan, Chief Corporate Officer, Balfour Beatty plc

"The regulatory framework is of critical importance to an industry like pharmaceuticals. Entrepreneurship, innovation and growth can all be obstructed by unnecessary or inappropriate regulation. I therefore warmly welcome the leadership shown by the UK in undertaking this work and in its commitment to address the problems identified.

Regulatory challenges must also be addressed at a European level. There is a real opportunity for the UK, working with the Commission and other Member States, to drive a regulatory agenda that will enable innovative industries such as life sciences to support more vibrant economies, more productive workforces, and healthier citizens. In light of the economic circumstances facing Europe, the need for constructive, concerted action in this area is greater than ever."

Eddie Gray, President, Pharma Europe, GlaxoSmithKline

“In its work programme for 2012, the European Commission focuses on growth and job creation. To realise that ambition across the European member states, it is vital that governments consider the impacts on business, especially when it comes to transposing and implementing European laws. As such, Kingfisher welcomes the Government’s refreshed approach on how to make European regulations less burdensome.”

Nick Folland, Legal and Corporate Responsibility Director, Kingfisher

“Worldwide economies face difficult times and it is welcoming that the UK and European Governments recognise the urgent need to encourage growth.

The principal engine of growth for advanced economies is innovation. Innovation requires entrepreneurs. Moreover, the greatest growth-creating innovations further require critical mass. As a small nation, the UK Government needs to achieve this by ensuring fast and efficient export. The natural first step outside the UK is Europe, but despite its size and wealth, trading across the area needs improvement. This report and the Government's wider EU growth agenda are steps in the right direction

The Government and the European Union can deliver the environment for growth but real gains will only be made if the direction and manner is left to entrepreneurs.”

Daniel Doll-Steinberg, Founder and CEO, Tribeka Limited

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Executive Summary

Last March, in the *Plan for Growth*[1], the Chancellor and Secretary of State for Business announced the Government would work with Balfour Beatty, GlaxoSmithKline, Kingfisher and Tribeka Limited to find ways to improve European growth opportunities for UK businesses. This included identifying where European enforcement could be improved and where EU laws could be made more growth-friendly. The review also sought to identify best practice when implementing EU legislation so that UK business can compete fairly.

The strategic messages from the UK businesses that the Government has worked with over the last eight months concern the need to:

1. reduce the overall European regulatory burden;
2. foster innovation; and
3. ensure the internal market realises its growth potential

if, as Europe we collectively wish to retain our economic importance and investment attractiveness in the global market.

On each of these, the Government is using the 16 specific case studies the businesses have provided as part of this Review to strengthen its arguments for action at European level.

For instance, to reduce the burden of forthcoming EU legislation, the Government will argue that proposed rules for assessing the ecological footprint of products should be voluntary and low-cost. To reduce the burden of existing laws, a future review of rules governing classification, labelling and packaging of chemicals should ensure that research and development samples are treated proportionately.

To foster greater growth through innovation, the Government will continue to work with industry to address regulatory barriers to manufacturing both at UK and European level, reiterate its call for risk-based approaches to chemical hazards, pharmaceutical manufacturing and product safety, and argue for effective European patent rules as well as SME access to finance.

To encourage growth by improving the functioning of the internal market, the Government calls for even application of rules for clinical trials, simplification of the EU rules on Value Added Tax and for greater harmonisation in the application of merger and acquisition rules.

The Government also sought to identify examples of UK gold-plating. This Review has not provided evidence of widespread gold-plating. Costly protection of species under the Habitats Directive was the one example. The Government today announces a review of the enforcement of this Directive with the aim of making it more even and predictable across the UK.

Introduction

This report presents the findings from the review announced in the March 2011 Plan for Growth to work with Balfour Beatty, GlaxoSmithKline, Kingfisher and Tribeka to find ways to improve European growth opportunities for UK businesses. This included identifying where European enforcement could be improved and where EU laws could be made more growth-friendly. The review also sought to identify best practice when implementing EU legislation so that UK business can compete fairly.

The strategic messages from the UK businesses that the Government has worked with over the last eight months are clear:

1. reduce the overall European regulatory burden;

2. foster innovation; and

3. ensure the internal market realises its growth potential

if, as Europe we collectively wish to retain our economic importance and investment attractiveness in the global market.

These messages reinforce the Government's existing EU growth strategy as published by the Prime Minister in March 2011 in the pamphlet *Let's Choose Growth*[2].

The businesses believe that to foster growth, both UK and EU regulation must be consistent, predictable, transparent and clear.

The Government is proactively working with allies to ensure new European proposals do not impose unnecessary burdens and foster innovation.

It is doing this by seeking to influence the European Commission early and by ensuring all three European institutions (Commission, Council of Ministers and the European Parliament) apply rigorous evidence to all their decisions. A particular consideration here is ensuring the disproportionate impact of regulation on the smallest businesses is properly assessed, and tailored approaches or exemptions applied where they can be.

To reduce burdens of existing EU regulation and to free up innovation, the Government is encouraging the European Commission to adopt a strategic programme of review with the overarching aim of ensuring European rules do not stifle growth.

The Government continues to argue for the proper functioning of the internal market.

The Government will use the 16 specific case studies that the businesses have provided as part of this Review to strengthen its arguments for action on each of these strategic messages at European level.

With the businesses, the Government also sought to identify examples of UK gold-plating. This Review has not provided evidence of wide-spread gold-plating, but the Government will continue to act on examples of gold-plating presented to us through the *Red Tape Challenge*[3] public review of existing legislation. In addition, the *Government's Principles for EU Legislation*[4] include strict guidelines for avoiding gold-plating when transposing new European directives into UK law. How these principles are being applied on a case by case basis across Government is being carefully scrutinised by Ministers.

The case studies are reproduced in full in Annex A. These are the submissions from the businesses as Government received them.

Who the four companies are

The four companies were chosen as representatives of business sectors where the UK growth potential is good, either because traditionally the UK has been particularly competitive or where, compared with other EU countries, the UK has potential to catch up. Tribeka Limited was chosen to represent small innovative companies with a business growth model based on strong exports both to the EU and globally. Tesco has provided an additional case study in the area of retail. To ensure the ideas reflect broader, sector-wide concerns, all case studies have been shared with key sector-specific industry organisations including the Mineral Products Association, the Association of the British Pharmaceutical Industry, the British Retail Consortium and the British Chambers of Commerce. The businesses' full submissions are printed in Annex A.

Balfour Beatty is a UK-based infrastructure and services business which builds and maintains roads, railways, airports, tunnels, bridges and more, with 50,000 people world-wide and 30,000 in the UK. Annually, it spends about £3 million on R&D. It operates in over 80 countries. Its growth over the last 10 years has been a mixture of organic growth and takeovers, with 50 per cent coming from acquisition over the last ten years, including companies in Germany, Italy, Spain and Sweden.

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. It employs around 98,000 people in over 100 countries and in 2010 spent £3.96 billion on R&D, £1.8 billion of which was spent in the UK. GSK also has a significant manufacturing presence in the UK, employing around 5,700 people. In 2010, Europe accounted for 27% of pharmaceutical sales, with 41% made in the USA and 32% in the rest of the world.

Kingfisher is a home improvement retail group with nearly 900 stores in eight countries in Europe and Asia. Its main retail brands are B&Q, Castorama, Brico Dépôt, and Screwfix. Kingfisher is investing £30 million in its Innovation Centre in Lille. Kingfisher has not submitted a specific case study but agrees with the overall conclusions of this review.

Tribeka Limited is a small, privately held company employing 30. It is backed by venture capital and is innovative with a world leading disruptive technology being deployed in USA, Europe and Australia. It has significant R&D expenses and its clients include Carrefour, Fuji, Microsoft, Sony and Tesco. Its revenues have grown over 400 per cent in the last 3 years and are expected to increase 300 per cent this year. More than 90 per cent of revenues come from export.

Following suggestions from the British Retail Consortium, the Government asked for supplementary evidence regarding the retail sector from Tesco Plc and Boots. Tesco provided an additional case study.

The importance of the European Union for the UK

The European Union remains the UK's largest trading partner, with 51 per cent of UK exports going to the single market[5] and 53 per cent of UK Foreign Direct Investment[6] coming from EU countries which in 2010-2011 alone generated 12,532 jobs, almost 30 per cent of all jobs generated by Foreign Direct Investment (FDI) that year.

All four companies that participated in this review and Tesco do business in Europe and have in the past grown because of the advantages the world's biggest single market has offered them.

However, all four have told the Government that unless the EU can address the issues raised in this report, it will become an increasingly uncompetitive location for businesses in which to operate.

Balfour Beatty sees most of its growth over the next 25 years coming from establishing its global business by expansion in Asia and South America, in addition to activity in Europe. This is because it finds these markets less difficult to expand into. GSK believes the pressure on the price of medicines, currently deflation of 3-5 per cent in Europe, will mean the European environment is increasingly difficult for the industry. Tribeka Limited is concerned about what it perceives as the stifling in Europe of innovation and entrepreneurial activity.

This business sentiment is reflected in more comprehensive surveys, stretching from the latest World Bank report where the only three European countries in the top 10 for doing business are Denmark (5), the United Kingdom (7) and Ireland (10)[7] to predictions by the Economist Intelligence Unit that as soon as 2020, the Brazilian economy will surpass Germany.

European growth through regulatory reform

The Government is committed to working with its European partners in Brussels and in other European Union capitals to foster growth by reforming the EU regulatory framework to reduce overall burdens.

Over the last 18 months, this commitment has delivered tangible results. Following concerted UK lobbying with partners, in October 2010, the Commission announced it would extend its standard period of consultation from eight to 12 weeks, giving the regulated more time to offer their views about whether a proposal is likely to deliver the desired outcome in the most effective way.

In March, June and October 2011, Heads of Government agreed in their European Council conclusions that Europe should reduce its overall regulatory burden and exempt the smallest of enterprises from both existing and new legislation where appropriate. On 23 November, the Commission said[8] it would exempt micro-enterprises from new EU legislation unless there is a compelling reason to include them. The Commission also published a list of existing EU obligations from which the smallest companies will be excluded.

Thirdly, in July 2011, to ensure amendments made by MEPs do not make European laws disproportionately burdensome, the European Parliament announced the creation of an internal unit with the specific remit of quantifying the impact of Parliamentary amendments to draft European legislative proposals.

Such progress is encouraging, but as the businesses have made clear, the need for concerted action is paramount: if the European Union is to retain its global competitiveness, it must ensure that both new regulatory proposals are rigorously outcome-focussed on fostering growth including through innovation, and existing laws are stringently reviewed for their continued effectiveness.

This report offers a number of specific examples where this process can be started.

1. Unlocking growth by reducing the overall EU regulatory burden

The businesses welcome the commitment by EU Heads of Government at March, June and October European Councils to reduce the overall EU regulatory burden. The challenge now is to ensure that this is applied in practice.

To make a reality of this commitment, existing smart regulation processes in the European Commission must be applied consistently, both to all proposed new legislation and all changes to existing legislation.

- Consultation with stakeholders on specific draft proposals in all cases must last a minimum of twelve weeks as the Commission has promised.

- All impact assessments must be vetted by the internal Commission body (the Impact Assessment Board) before they are allowed to progress to adoption by the College of Commissioners. The number of IAs must be increased from the 27 per cent of proposals that are currently accompanied by fully quantified impact assessments[9].

- The Commission's test for impacts on SMEs needs to be done more frequently and its recent commitment to exempt micro businesses from new EU rules from 2012 must be applied in practice.

There is a simple way in which the European Commission can further improve the quality of its proposed legislation.

The UK Government and the businesses it has worked with, believe that consultation with stakeholders should include not only specific proposals, but also accompanying draft impact assessments. In that way, stakeholders, including businesses, would have even greater chance to ensure Commission regulatory plans are carried out in the most appropriate, least burdensome way.

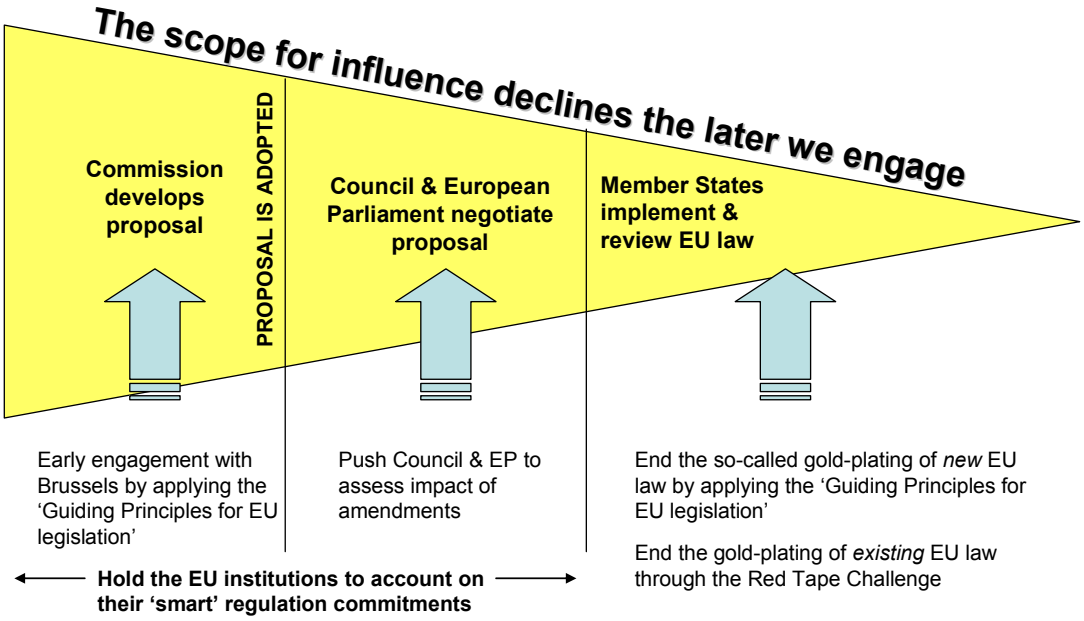
Both the European Parliament and Council must now finally act on their 2005 commitment to assess the impact of substantive amendments made to legislative proposals[10].

For its part, the European Parliament must now ensure that its newly created internal unit does in fact quantify Parliamentary amendments to draft legislation proposed by the Commission. Finally, the Council too has a duty to ensure that it puts in place a system that allows it to carry out its commitment to quantification of amendments.

Influencing Brussels early

Both the businesses and the UK Government welcome the improved transparency that the Commission has adopted for its forward work programme over the last few years.

The Government's approach to reducing the overall EU regulatory burden



Reducing burdens by amending two forthcoming EU proposals

Tribeka has used this transparency to raise specific issues relating to forthcoming proposals which are part of Commissioner Barnier's Single Market Act. The Government has committed in its *Guiding Principles for EU Legislation*[11] to engage with the European Commission before it has adopted proposals to increase UK influence on the drafting of legislative proposals.

1.1 Corporate Reporting

Tribeka argues that any Commission proposal for greater mandatory corporate governance reporting on social, environmental and human rights issues will increase administrative costs greatly for SMEs, inhibiting product expansion and export opportunities. It suggests an SME exemption.

The Government has just finished consulting on a domestic proposal for a new reporting framework for companies, including a UK approach to corporate reporting on social, environmental and human rights issues. This consultation will inform both domestic plans and the UK's view of the Commission's proposal expected in 2012.

1.2 Environmental Footprint requirements

The European Commission has published draft environmental footprint methodologies for products and organisations, including carbon emissions and other environmental impacts e.g. water, toxicity. They are also currently considering policy options for how to implement the methodology.

Tribeka argues that should such a system be made mandatory, the additional burden would pose an unacceptable cost to SMEs and lead to companies taking their innovation outside the EU.

The Government is committed to working with the European Commission to ensure that the development of their environmental footprint methodologies are harmonised as much as possible with existing schemes and are straightforward for business to apply.

Reducing burdens by reforming existing EU regulation

Other suggestions put forward by the businesses concern proposed changes to existing European legislation.

The Government welcomes the Commission's commitment in October 2010[12] that evaluation of legislation should be an integral part of its policy cycle and believes the following suggestions from businesses should be carefully considered as part of the Commission's new programme of evaluation and more broader policy area reviews which it is calling 'fitness checks'.

1.3 Exempt R&D pharma samples from disproportionate notification requirements

GSK has highlighted that sample substances used for Research & Development (R&D) purposes (i.e. non-commercial) are subject to the same classification and labelling requirements when being transported between its various sites and subsidiaries (and therefore not placed on the open market) as products being placed on the market. This is regardless of the sample size. Since the regulation concerning the classification, labelling and packaging of chemicals (CLP) came into force in January 2009, GSK has had to register hundreds of compounds, many of which were handled in small quantities and only for a short period of time.

The Government agrees that current rules impose unnecessary burden on business and took this view during the negotiation of the original regulation. A review of the regulation is expected in 2012 and the UK will work with other Member States and the European Commission to press for reform at European level.

1.4 Meeting consumer demand: lifting the regulatory barrier to low alcohol wine

Tesco would like to meet the increasing consumer demand for low alcohol wines as part of its efforts to encourage responsible drinking. Currently within the EU, low alcohol wine may (with a few exceptions) generally only be described as wine if its alcohol content meets or exceeds 8.5 per cent by volume. Tesco argues this means that consumers are not given the choice that is afforded by recent advances in wine production technology. This regulatory prohibition is also limiting consumers who wish to choose low alcohol wines for health reasons.

The Government strongly supports Tesco's position and hopes to advance any measure that could give consumers more choice. This new category could also afford innovative producers the opportunity to fulfil the growing demand for alternatives to regular drinks.

Other EU wine-producing countries share the UK position and the Government will be working with them in putting forward this call for change to EU legislation.

1.5 Commercial Agents Regulations

Tribeka raised with the Government the difficulty small businesses in particular face when they wish to expand into a particular EU country. Often local agents can help UK SMEs distribute or market their goods or services in other EU countries by applying local knowledge and networks.

However, the European rules (Commercial Agents (Council Directive) Regulations 1993) are weighted so much in the local agent's favour that UK SMEs are put off employing the services of local agents and conclude there is no future for their business in these new European markets.

The Government is considering whether more readily available guidance would clarify obligations and encourage more use by UK SMEs of commercial agents to expand export opportunities in the EU.

2. Innovative Europe – Growing Europe

Tribeka and GSK argue passionately for the EU to create conditions that foster rather than undermine innovation.

Tribeka told the Government as part of this review that it believes the greatest threat to growth in the EU is what it perceives as a culture of stifling innovation. The company believes contributing factors to this climate of lacking innovation are the increase in regulation and the inability for small companies to tap the benefits of the many cultures across Europe and the diversity to innovate. The consequences of not addressing this could lower the EU's competitiveness and companies choosing to innovate elsewhere in the world.

As a large multinational at the cutting-edge of medicines development, GSK also argues that a significant hurdle to the adoption of innovative technologies is that regulations and guidelines do not always keep pace with rapid developments in science. As a consequence, a new technology or innovative approach may need to be introduced where regulatory provisions do not exist or have not been sufficiently developed, or where there is a lack of understanding/knowledge of the new technology by the regulators. This can result in a competent authority taking a risk-averse approach, thereby creating a regulatory barrier that stifles innovation through delaying its introduction.

As part of this review, GSK has provided its vision for the future, challenging the Government and the relevant regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), to be an even brighter regulatory beacon in Europe and globally, more progressive in its approach to new technology, and even more active in promoting innovation. The MHRA is in discussion with GSK about how it can deliver this vision while at the same time ensuring that medicines and medical devices are safe.

Crucial to the examples below for greater innovation potential, is a risk-based approach to regulation. GSK has provided the following examples where it believes an innovative approach has been undermined because of a limiting regulatory environment.

Three ways to foster pharmaceutical innovation

2.1 Innovation through simplifying pharmaceutical manufacturing

Historically, the usual approach to pharmaceutical manufacturing is two-step: to produce the active pharmaceutical ingredient (API) and then turn it into a product people can use such as a tablet or capsule.

GSK investigated ways of trying to combine elements of these processes so as to optimise the manufacturing process, enhance the effectiveness of medicines, and reduce their final cost.

However, the EU's Committee for Medicinal Products for Human Use (CHMP) Quality Working Party Guidelines and current international guidance do not facilitate the optimisation of the manufacturing process as they reinforce the separation of the two steps. GSK has therefore not pursued this promising technology, resulting in costs which could otherwise be eliminated from the manufacturing process.

The Government will continue to work with industry to address concerns about regulatory barriers to innovation stemming from the EU and elsewhere.

2.2 Innovation by applying new manufacturing technologies

Recently GSK has been developing and applying a new approach to pharmaceutical manufacturing. This has involved adapting processes long used in other manufacturing industries to pharmaceuticals. The potential gains are improvements in precision, lower costs and manufacturing processes that are easier to control. GSK has now decided to invest in this process for the manufacture of tablets.

Although this is an exciting development for GSK, and one in which the company is an industry leader, the decision to innovate could have been made a lot earlier. The principles and techniques have been on GSK's radar for the past 15 years, but the company felt it could not give the green light to invest in this technology. Implementation of guidelines ICH Q8, Q9 and Q10 offers the UK an opportunity to create a more supportive regulatory framework for the adoption of innovative technologies in the future. Had GSK invested earlier in this innovation, the UK may have been more competitive today, enabling competition with lower cost pharmaceutical manufacturing in emerging markets such as China and India.

The MHRA will continue to work with industry to address concerns about regulatory barriers to innovation stemming from the EU and elsewhere.

2.3 A return to a risk-based REACH to keep the EU innovative and competitive

Since 2007 the rules for the registration, evaluation, authorisation and restriction of chemicals in the EU are governed by the REACH Regulation.

According to GSK, 2010 changes to guidance issued by the European Chemicals Agency do not take sufficient account of established risk-based approaches and could entail additional costs to install new containment of £80,000 per registered intermediate or additional costs of up to £150,000 per tested substance. The use of significant numbers of animals is also required under these regulations. GSK believes this runs counter to consideration of the 3Rs (replacement, refinement and reduction of animals in research) and minimisation of animal use which is an important priority for the company.

These costs could be incurred because the company will have to apply what it believes are unrealistically stringent engineering control measures for intermediate substances that do not take into consideration available hazard data and therefore do not actually increase workplace health and safety.

In addition, the new requirements could significantly affect the competitiveness of the EU-based supply chain for active ingredients.

The Government is working with GSK to determine scope for pushing for a more pragmatic approach by the* European Chemicals Agency*, or as part of the forthcoming 2012 European Commission review of REACH.

Boosting SME innovation

Tribeka has raised both the lack of an EU patent and the prospect of more European regulation as specific examples holding back EU innovation driven by SMEs.

2.4 Single European Patent

Tribeka draws attention to the lack of a single patent covering the whole EU. They also cite the high cost of patent applications and their administration as placing a further barrier to innovation, particularly as fees are not refunded if the application is unsuccessful. Further, they find that innovative use of established technology often cannot be patented. Tribeka believe these factors make venture capital funding harder to raise and damage the intellectual property environment for innovation.

Following the latest round of negotiations commencing in 2000, a general approach on regulations implementing enhanced cooperation for unitary patent protection was agreed by EU Competitiveness Ministers in June 2011. These draft regulations are being considered by the European Parliament. In parallel, progress is being made on an international agreement to set up a unified patent court. The system may be in place from 2015.

Where firms are interested in obtaining Europe-wide patent protection, costs should be lowered substantially compared to maintaining a patent in all the relevant individual jurisdictions. Translation costs will also fall and significant savings will be possible once transitional arrangements have ended.

The independent Hargreaves Review[13] reported in May on how the intellectual property system can better support growth and innovation. The Government will explore with Tribeka their specific comments on how to ensure an intellectual property environment that fosters innovation, including how this can impact positively on venture capital funding.

2.5 Product safety harmonisation

Tribeka suggests that an expected proposal to revise the General Product Safety Directive should exclude SMEs so that innovation is not driven outside the EU.

The Government's position is that only universal application of these rules can ensure that products are safe for consumers and workers.

Nonetheless, the Government agrees that a 'one size fits all' approach to enforcement could impose over-engineered quality control systems on the smallest businesses. Disproportionate burdens such as these could potentially put off SMEs from innovating and bringing new products to market. There is an existing provision for taking into account business size when assessing whether appropriate quality control systems are in place.

The Government will ensure that negotiations at the EU level consider similar ways of avoiding disproportionate impact on the smallest businesses.

2.6 Unleashing venture capital investment for SMEs

Tribeka raised the importance of improving small business access to capital markets. It would like to see the benefits of Business Angels improved and for the EU to look to other countries such as Israel to learn how they have managed to greatly improve SME access to capital. Tribeka warns that if this does not improve, innovation will be taken outside of the EU.

The UK welcomes the European Commission's proposals to improve access to capital markets for high growth potential and innovative small and medium-sized businesses (SMEs). Support for SMEs is at the cornerstone of the Government's growth strategy, and we know this cannot happen without increased access to finance.

The Government has been closely engaged with the review of the EU's Market in Financial Instruments Directive, including looking at the impact of the Directive on Business Angel investment. We note Israel's considerable success at encouraging venture capital and are looking closely at international best practice in order to ensure that the EU will be able to boast world-leading SME access to finance.

3. Completing the European Single Market – realising long-term growth

Regulatory barriers persist to UK companies' trade in the single market.

As part of this review, the businesses have made clear that allowing the world's largest marketplace to function better must remain a top priority for the EU.

The potential for gains is great. The Single Market already adds €600 billion a year to our economy[14]. Further liberalisation of services and the creation of a digital single market could add €800 billion more[15].

If the EU wishes to remain globally competitive, short-term measures of national protection should therefore be turned into long-term growth opportunities by opening up the market fully. All four companies have provided clear examples of where the internal market is not working effectively.

This chequered picture is one reason why Balfour Beatty, for example, sees its long-term growth predominantly outside, not within the European Union.

3.1 Acquired Rights Directive: Simplifying Merger and Acquisition Rules

Balfour Beatty says that its merger and acquisition activities (M&A) in Germany have run into added expense due to how the Acquired Rights Directive is applied in the country.

According to Balfour Beatty, it is only very late in the process of M&A that the company finds out whether the German workforce actually wants to remain with the new / merged company. This can mean that companies do not actually get what they thought they paid for.

In the UK, workers have the right not to transfer, but in such cases the employment is terminated by the transfer, though it is not a dismissal. In Germany, under the Civil Code, employees have the right to object within one month (either to the new or existing employer) of being informed about any transfer and have the right to remain in their initial employment.

The Government has launched a call for evidence on the effectiveness of current TUPE regulations in the UK as part of the Government's wider Plan for Growth.

Following feedback from Balfour Beatty, the Government will now also include in this consultation questions relating to the implementation of TUPE in other EU Member States. The Government is also exploring in more detail the particular issues raised through our overseas network. Initial findings indicate that the issues Balfour Beatty raise relate to the German Civil Code (as noted above) rather than the Acquired Rights Directive per se.

3.2 Harmonising the implementation of the Clinical Trials Directive

GSK has raised the non-uniform application of this directive across the single market.

This means added complexity, increased costs and delays to trials because businesses must deal with multiple competent authorities, multiple and non-uniform information requirements, and the need for national versions of the protocol.

GSK supports the following: (i) establishing an independent Health Research Authority in the UK that should streamline ethics and specialist approval; (ii) standardising the format and content of clinical trial applications; (iii) introducing risk adaptation of the requirements for clinical trials; (iv) introducing a new optional process for multi-country trials; and (v) all safety reporting to be centralised in one database.

The Government agrees that the current differences in implementation of the directive across the EU States add complexity, administrative burden and cost to UK businesses who wish to conduct multi-country trials.

The European Commission will publish proposals for 2012 on revising the directive and the Government is playing a leading role in Europe to meet industry needs and concerns. The Government has lobbied specifically to:

- Reduce the burden to business of monitoring trials by promoting UK best practice, which ensures that regulatory oversight is proportionate to risk
- Simplify the clinical trials application process by agreeing standardised format and content, so that business doesn't have to navigate multiple national requirements. Whilst the CTD and underpinning guidance sets out standard requirements for approval of clinical trials, the problems arise because many member states have added their own national requirements. An important aim of the revision of the CTD is to reduce the scope for national variations and to simplify applications for multi-state trials through the use of technology
- End multiple reporting of 'suspected unexpected serious adverse reactions' (SUSARs) during clinical trials by adopting centralised reporting to a single EU database. However, the UK will only be able to support single reporting of SUSARs to a central (EU) database once it has been clearly demonstrated that it has the means to immediately send on relevant SUSARs to the appropriate national competent authority. The UK also supports clearer guidance on SUSAR reporting and removal of the requirement for sponsors to report SUSARs to Ethics Committees
- Reduce uncertainty for businesses conducting multi-country trials by adopting a simple non-bureaucratic procedure that does not routinely re-open the original decision to proceed – provided that there is a means for review if serious public health issues are identified.

3.3 Variations Regulation

GSK has raised that although the Variations Regulation came into effect in January 2010, the legal text for mandating the application of the new rules to national variations is not yet finalised. GSK has warmly welcomed the UK's decision to voluntarily adopt the new rules. However, without mandatory application of the new rules across all Member States, business must cope with different national regulatory requirements still in effect across many Member States.

GSK estimates resulting costs of US$100 million across the business's operations. GSK would like to see the Commission produce mandating text and a date for mandatory implementation as soon as possible, so that it, and the pharma industry generally, can finally reap the benefits of this better regulation initiative.

The Government agrees that the Variations Regulation should be extended to purely national marketing authorisation as soon as possible.

The Government will call on the European Commission to speed up the adoption of the required amendments, and to press for a timely implementation date across Member States.

Any changes to the Variations Regulation should not add complexity as this will have a negative impact on both industry and regulators alike.

3.4 VAT and domestic supply

Tribeka raised the difficulties and problems associated with the EU VAT system for goods bought into and traded within the internal market as a barrier to efficient business.

Following widespread consultation, the European Commission is expected to publish a White Paper on the future development of the EU VAT system at the end of this year. The Government contributed to this review and plans to get closely involved in further consultation launched by the Commission to share best practice and develop practical solutions to common VAT problems.

The Government will work with Tribeka to ensure this issue is fed into the wider European VAT reform process.

4. Ending UK Gold-plating so UK companies are not disadvantaged

This review has not suggested there is widespread evidence that the UK gold-plates when implementing European directives. One example has been put forward by Balfour Beatty. It concerns the implementation of the Habitats Directive where the Government today announces it will review UK implementation and seek to harmonise enforcement across the UK.

4.1 Consistent implementation offering pragmatic species protection

Balfour Beatty has identified the EU's Habitats Directive and in particular requirements for the protection of the Great Crested Newt as both highly costly and time-consuming adding £20,000 – 40,000 to every major construction project.

The Government today announces a review of the Birds and Habitats Directives as currently implemented in England by Budget 2012, with a view to reducing the burdens on business while maintaining and where possible enhancing environmental benefits.

We want to ensure that we maintain our biodiversity whilst making it straightforward for the construction industry to deliver the infrastructure that this country needs for growth and prosperity. This will not only make the UK a more attractive destination for investment, but also deliver important jobs and greater value for money for the taxpayer as construction costs fall.

Even though this review did not highlight widespread gold-plating, the Government remains strongly committed to acting on its *Coalition Agreement*[16] to 'end the so-called gold-plating of EU regulations'. The Government will continue to act on examples of gold-plating presented to it through the Red Tape Challenge process of public review of existing legislation. In addition, the Government's Principles for EU Legislation include strict guidelines for avoiding gold-plating when transposing new European directives into UK law. How these principles are being applied on a case by case basis across Government is being carefully scrutinised by Ministers.

5. More UK priorities for EU regulatory reform

In addition to this review, the Government's Red Tape Challenge public consultation of regulations, and business organisations have highlighted further examples where European legislation should be reformed to improve growth.

The Government is including these suggestions in its broader EU growth strategy set out in this report. In addition to the sixteen case studies put forward by Balfour Beatty, GlaxoSmithKline, Kingfisher, Tesco and Tribeka, the Government will:

- Re-affirm its commitment to the opt-out of the 48 hour week imposed by the Working Time Directive;
- Announce the intention to use the Commission review of REACH to remove any barriers in the current system;
- Affirm commitment to negotiate to maintain a proportionate regime and resist elements which would hinder growth in proposals related to the Posting of Workers Directive;
- Work with the European Commission and other Member States to ensure that forthcoming fitness checks and consultations on proposals for revisions to the Air Quality, National Emission Ceilings and freshwater legislative framework include an assessment of impacts on the economy and economic growth as an objective, while still allowing us to continue our drive to reduce air and water pollution, so as to lead to a more balanced outcome.

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ANNEX A: BUSINESS SUBMISSIONS

BALFOUR BEATTY: Pro forma – TUPE

Improving European growth opportunities for UK business: case studies

1. What is the regulatory issue affecting your business?

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else?

TUPE legislation is currently applied in an individual basis by EU states leading to major variances across Europe. In the UK staff are automatically transferred from the existing to the new employer following a change in the contract provider. In the same situation staff in EU states such as Sweden and Germany staff have a democratic right to decide if they wish to transfer to the new employer. This situation results in a company bidding for contracts in EU states outside the UK with a large degree of uncertainty over the status of workforce involved to undertake the activity required under the contract and in the UK context the new contractor has to bear the cost of any restructuring needed.

Please identify the specific EU regulation affecting your business.

The difference in interpretation of TUPE legislation is not derived from an EU Directive.

What business activities are affected?

All business activity involving the transfer of staff following a contract gain resulting in a change of employer.

How recurrent / common is the problem?

How do you currently deal with the situation?

The current situation creates an additional level of uncertainty in contractual negotiations which in turn has an impact on cost. Companies factor this cost into their bidding process, cost and offer.

Is your experience of the regulation/s in other Member States different?

In the UK staff are automatically transferred to the new contractual provider following contract closure. In Sweden and Germany staff have the option to decide if they wish to transfer to the new contract provider. Whilst there is uncertainty about costs if the staff don't transfer it is the new contractor who in the UK context has to bear the cost of any restructuring needed. Although this will be incorporated into the tendered costs for the provision of service.

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

Efforts should be made to introduce a standardised EU wide TUPE guidelines which would introduce a level of consistency across the EU.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

This solution would require a change to EU legalisation and could be sponsored by the UK Government.

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

The automatic transfer situation in the UK creates a degree of certainty to the bidding process which should be replicated through the EU.

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

The change would remove a level of unnecessary risk to the contract bidding process which would reduce costs and encourage greater competition for which would ultimately benefit the tax payer and consumer.

3. Can the impact be monetised?

Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1

There is certainly administrative burden in having to understand the various ways in which TUPE is applied in other countries within EU.

The costs

Be as specific as you can although order of magnitude is also useful

What is the nature of the costs accrued? *Eg*.

Transaction costs

Opportunity costs

Administrative burden

BALFOUR BEATTY: Protected Species

1. What is the regulatory issue affecting your business?

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else

In the UK, we are required to protect a range of species under the Habitats Directive 92/43/EEC. Great Crested Newts are widespread across Britain and relatively common (unlike other regions of Europe where they are considered rare). Considerable time and effort is expended in the protection of Great Crested Newts in the UK to comply with the Conservation of Habitats and Species Regulations 2010 and associated regulations, implementing the Habitats Directive. Measures include the installation of newt fencing, managed relocation and monitoring by ecologists.

These measures impact on the delivery of construction projects (particularly civil engineering schemes) and money spent on their protection could be better deployed on other ecological initiatives focused on enhancement rather than protection.

Please identify the specific EU regulation affecting your business

Habitats Directive 92/43/EEC.

What business activities are affected?

UK wide construction activity.

How recurrent / common is the problem?

The problem is very common and is currently affecting activity on the M25.

How do you currently deal with the situation?

Our mitigation measures include the installation of newt fencing, managed relocation and monitoring by ecologists.

Is your experience of the regulation/s in other Member States different?

Great Crested Newts are widespread across Britain and relatively common but considered rare in other regions of Europe.

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

As the Great Crested Newt is a common species in the UK it does not require special protection in law, therefore they should be removed as category covered by the Directive. Effort would be better directed to habitat enhancement.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

The change suggested above would require a change to the Directive.

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

Balfour Beatty has not experienced this problem in other EU states.

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

An amendment to the Directive would not in itself ease access to EU markets but there would be a reduction in construction cost which can only strengthen the company's competitive position.

3. Can the impact be monetised?

Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1

Our major civil engineering business alone spent approximately £0.25m on newt protection measures such as fencing and ecological advice (in the order of £20-£40k for each major project). Overall, therefore we would estimate costs in the order to several hundred thousand pounds across our business as a whole.

Be as specific as you can although order of magnitude is also useful

What is the nature of the costs accrued? *Eg*.

Transaction costs

Opportunity costs

Administrative burden

BALFOUR BEATTY: Waste Directive

1. What is the regulatory issue affecting your business?

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else

The Waste Framework Directive (2008/98) introduced a definition for when a discarded material or substance becomes a waste. When applied in a construction context, case law has demonstrated that clean uncontaminated waste soils when moved from one site to another are 'waste' and therefore require costly permits to be in place for the 'reuse' of this material.

The Environment Agency have taken an overly cautious approach to avoid contravening EU law and we are now in a position where there is no agreed UK law defining uncontaminated soils as non-waste. The closest we have is an Environment Agency position statement stating that if the CL:AIRE code of practice is applied to these materials (bureaucratic in itself) then the Environment Agency will take no enforcement action.

We need clear references in UK law that defines that clean uncontaminated soil material is not classed as a waste thus removing the need to either apply for a permit or implement the CL:AIRE code of practice.

Please identify the specific EU regulation affecting your business

The Waste Framework Directive (2008/98)

What business activities are affected?

UK Construction activity.

How recurrent / common is the problem?

This is common throughout the UK.

How do you currently deal with the situation?

Balfour Beatty complies with the Directive through the purchase of permits.

Is your experience of the regulation/s in other Member States different?

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

Provide clear advice / regulatory position statements that obviously uncontaminated soils are not waste and do not require the CL;AIRE. Code of practice to be followed.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

This recommendation requires a change in UK Directive interpretation.

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

The consistent EU wide implementation of this Directive would not in itself ease access to EU markets but there would be a reduction in construction cost which can only strengthen the company's competitive position.

3. Can the impact be monetised?

Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1

Costs not readily available but we would estimate the relative magnitude to be in the order of several £hundred thousand through the unnecessary use / importation of clean top soil to construction sites when there is insufficient time to follow the bureaucracy of the CL;AIRE code of practice.

Be as specific as you can although order of magnitude is also useful

What is the nature of the costs accrued? Eg.

Transaction costs

Opportunity costs

Administrative burden

GSK

GSK: REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) – Registration of intermediates

1. What is the regulatory issue affecting your business?

Please identify the specific EU regulation affecting your business

EU REACH Regulation EC 1907/2006 - REACH is a European Union regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. It came into force on 1st June 2007.

REACH has several aims:

- To provide a high level of protection of human health and the environment from the use of chemicals.
- To make the people who place chemicals on the market (manufacturers and importers) responsible for understanding and managing the risks associated with their use).
- To allow the free movement of substances on the EU market.
- To enhance innovation in and the competitiveness of the EU chemicals industry.
- To promote the use of alternative methods for the assessment of the hazardous properties of substances e.g. quantitative structure-activity relationships (QSAR) and read across

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else

The pharmaceutical industry manufactures, imports and purchases chemical intermediates from EU contract manufacturing partners. These intermediates are the building blocks that are used to make a drug substance which in turn is formulated into the drug product or medicine. Article 2(8) of REACH exempts intermediates from the general registration requirements referred to in chapter 1 title II of REACH. Instead a **manufacturer/importer of intermediates has to register his substance under a different regime** as specified in chapter 3 of Title II that provides for a reduced test package for registration. The registrant of an intermediate must first fulfil requirements set out in Articles 17 (3) or 18 (4), one of which includes ensuring that the substance is "rigorously controlled by technical means during its whole lifecycle".

Substances registered as intermediates are not subject to authorisation (Title VII). These provisions take into consideration the reduced potential for widespread environmental distribution and exposure to intermediates compared to general chemicals.

EU Level Guidance

It is generally accepted that hazard data required to reduce risk of exposure to chemical intermediates should be lower than those for chemicals with wide dispersive use. Chemical intermediates are typically handled using a risk-based approach so that control measures are assigned based upon known hazard potential. This approach was reflected in the European Chemicals Agency (ECHA) Guidance issued prior to December 2010.

However **in December 2010** ECHA issued **revised guidance** that made assignment of a substance as an intermediate subject to manufacturers/importers meeting **unrealistically stringent engineering control measures** in order to "demonstrate rigorous control". This precautionary approach does not take into consideration availability of hazard data that would allow for a **more risk-based control strategy**.

The consequence of this change in guidance is that registrants will either have to invest in expensive over engineered control strategies if they wish to describe their substance as an intermediate or undertake Article 10 testing as a "substance" which is both expensive financially but also has an additional impact in terms of requiring the use of significant numbers of animals as part of the testing. Any additional animal testing should comply with the principles of the 3Rs (the replacement, refinement and reduction of animals in research). It is our view that the compounds the REACH legislation applies to are only handled for brief periods, and our current guidance for receiving and handling isolated intermediates are sufficient. These controls are aligned to the long-standard Occupational Exposure banding system, which takes account of the nature and quantity of hazard data, the principles of which are used throughout the pharmaceutical industry. . Neither approach included in the guidance will improve protection to human health nor the environment compared to existing provisions.

What business activities are affected?

This change in guidance predominantly affects manufacturing operations in Europe. This affects the Pharmaceutical company but more significantly also SMEs that act as contract manufacturing partners to the sector.

How recurrent / common is the problem?

Very common. To make one drug substance, there may be up to 10 isolated intermediates manufactured or imported that require REACH registration.

Is your experience of the regulation/s in other Member States different?

There is no legal certainty how different member states will enforce the revised ECHA Guidelines on Intermediates.

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

It is clear that the December 2010 ECHA Guidelines for intermediates have to be revised so that a risk-based approach to registration of intermediates can be offered. The current approach recommended in the guideline is contrary to two of the stated aims of REACH. Namely those of enhancing innovation in and the competitiveness of the EU chemicals industry, and reduction in animal use.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

Requires revision of the guidelines to make it clear that a risk-based approach can be adopted to meet strictly controlled conditions if hazard data are available.

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

No

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

Too early to tell.

3. Can the impact be monetised?

Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1.

Each of our EU Chemical Manufacturing plants has approx 10 materials that we consider on-site or transported intermediates in the 10-100 tonnes per annum (tpa) volume band that have been pre-registered. The worst case scenario is that we cannot demonstrate strict control in a manner that complies with current ECHA guidelines and a REACH Annex VIII test package costing £150,000 would be required for each substance. This would cost each site an additional £1.5 million.

It is highly likely that the costs incurred as a result of the REACH guidance for intermediates will significantly impact the competitiveness of the EU-based supply chain compared to the growing capacity of suppliers located in developing markets.

GSK: CLP (Classification, Labelling and Packaging of Chemicals) – Notification of samples

1. What is the regulatory issue affecting your business?

Please identify the specific EU regulation affecting your business

EU CLP Regulation EC 1272/2008 - CLP is a European Union regulation concerning the Classification, Labelling and Packaging of Chemicals. It came into force on 20th January 2009.

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else

GSK is a global business that relies on collaborations between company sites and external groups such as universities, Contract Research Organisations etc.

To support Research and Development, the pharmaceutical industry transports and/or imports many thousands of small samples between legal entities. Many of these samples are classified as hazardous according to the criteria described in CLP and are packaged and labelled accordingly. They are typically handled by trained scientists under controlled conditions and are not placed on the open market. Samples can be as small as a few milligrams and with product attrition within the R&D lifecycle, many of these substances are used only for a short time.

One requirement of the CLP regulation is that companies are mandated to notify the classification and labelling elements of substances to the classification and labelling inventory established at the European Chemicals Agency (ECHA) if they are placed on the market *(CLP Article 40).* There is no provision or exemption for research and development samples if they are transported between legal entities and there is no volume trigger exemption (no lower tonnage threshold). This means that even the smallest sample would require notification if classified as hazardous; in another scenario, a candidate molecule which is initially progressed and then discounted would still need to be notified.

This regulation has resulted in GSK notifying several hundred compounds in our early development pipeline and because new data are regularly generated, we must provide frequent updates. We believe that the requirement to notify research and development samples to the classification and labelling inventory does not add to the stated aims of the Notification Inventory, is an activity that creates bureaucracy, and requires resource on behalf of the registrant and the ECHA for no purpose.

What business activities are affected?

Pharmaceutical Research & Development Operations

How recurrent / common is the problem?

Frequent. Several hundred notifications were made to meet the first deadline of 1st Dec 2010 and we are making many new notifications per month as new compounds are evaluated for their hazardous properties or new hazardous properties are identified.

How do you currently deal with the situation?

We have assigned resource to make the required notifications to the ECHA (see below)

Is your experience of the regulation/s in other Member States different?

No

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

Whilst we support the need to classify and label research and development samples to provide health and safety information to our employees and collaborators, we believe that **research and development operations should receive a full exemption** from the need to notify to the classification and labelling inventory.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

Would require changes to the European Legislation

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

No

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

Too early to tell.

3. Can the impact be monetised?
Difficult to estimate but, for example the administrative cost of a person updating the database on top of daily activities would come to approximately £25,000 across GSK
Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1. This requirement to notify substance information to ECHA for materials in the R&D phase of the Business is bureaucratic, takes up valuable administrative resource, and does not add any value in terms of protection of human health or the environment.

GSK : EU Clinical Trials Directive

1. What is the regulatory issue affecting your business?

Please identify the specific EU regulation affecting your business

EU Clinical Trials Directive - Directive 2001/20/EC – which was introduced into law in 2001, and fully implemented by all EU Member States from 2004.

The primary purpose of this Directive was to ensure:

- The protection of the health and safety of clinical trial participants;
- The ethical soundness of the clinical trial;
- The reliability and robustness of data generated in clinical trials; and
- Simplification and harmonisation of the administrative provisions governing clinical trials in order to allow for cost-efficient clinical research.

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else

Overview

Non-uniform implementation of the EU Clinical Trials Directive across Member States – this divergent approach adds to the complexity, number of tasks performed, and the inability to reuse documentation for different Member State National Competent Authorities (NCA).

Detail

- **Multiple and divergent assessments of clinical trials applications in different Member States** – for multinational trials, result is increased cost and complexity to address multiple competent authorities questions on the application, the need for national versions of the protocol, and delays to the initiation of the trial across different Member States.

- **Variation in application of safety reporting requirements** – all relevant information about suspected unexpected serious adverse reactions ("SUSARs") must be reported to the NCA and the Ethics Committee (EC) of the Member State concerned, which then reports them to a Community database. Different approaches in Member States leads to multiple reporting of the same SUSAR, lack of reporting, and unreliability of the Community data on SUSARs - reducing the NCAs' ability to monitor safety data, and thereby to address potential risks for clinical trial participants.

- **Lack of common definition of Investigational Medicinal Product (IMP)** – is leading to differential application of the definition and accompanying guidelines for interventional and observational trials across Member States. For example, even with the common scenario of a 2-arm study of New Chemical Entity (NCE) + baseline therapy, versus placebo + baseline therapy, in some Member States the baseline therapy is regarded as IMP, in others it is not. This adds to the complexity, number of tasks performed, and the inability to reuse documentation for different Member State NCAs.

- **Differing classification of Substantial Amendments in different Member States** – leading to companies over-notifying amendments to avoid potential non-compliance, with associated additional resource requirements.

What business activities are affected?

All functions in GSK involved with the initiation, conduct and oversight of clinical trials, whether single or multi-country (e.g. regulatory affairs, clinical operations, clinical trials supplies, compliance and pharmacovigilance), are impacted.

How recurrent / common is the problem?

Ongoing and persistent – All clinical trials involving more than one member state in the EU are impacted. Even for clinical trials in a single member state, it would be simpler if a standardized set of requirements existed.

How do you currently deal with the situation?

We have to maintain a central database of each country's CTA requirements. This is frequently updated as individual Member States amend their requirements, expectations of the data we submit or request information in particular formats of the documentation, file nomenclature, file structure and submission structure. No two Member States have the same requirements. We then create single or multiple copies (depending on the requirement) of each Member State CTA dossier for submission to the individual Member State authorities.

Following the CTA submissions, authorities use different procedures and timelines for the review. Rarely is there any similarity in the questions or issues raised by different authorities in the review of a CTA. Different authorities request responses to their issues within different timescales ranging from about 10 days to 90 days.

Is your experience of the regulation/s in other Member States different?

All the Member States have subtly different regulation. No one Member State stands out as having better regulation than the others.

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

We support the creation of an independent Health Research Agency (HRA) that would seek to incorporate and streamline the existing ethics and specialist approvals (e.g. use of patient data and tissues). The HRA and regulatory and governance bodies in the devolved nations should work by agreement to develop a seamless approvals system for the whole of the UK, for all aspects of its remit. Most importantly it should house a new NHS National R&D Service (NRDS) for England.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

At the EU level, the Commission itself is proposing a **revision of the Directive**. We support this **subject to inclusion of the following points**:

- A **standardized format and content** of the clinical trial application (CTA) for all Member States that reflects the 'core' requirements in current European Commission guidelines, rather than a list of all current national requirements.

- Introduce **risk adaptation** into the regulation of clinical trials, such that the regulatory requirements for low risk trials is minimized as much as possible.

- For multi-country clinical trials in the EU, a new, optional process is required that:
    - Is non-bureaucratic, simple and speedy
    - provides uniformity of conduct of a trial in all concerned Member States
    - ensures there is consistency between EU level scientific advice and the assessment of the clinical trial
    - establishes a clear demarcation in the remit of the regulatory agencies and the ethics committees
    - allows the inclusion of centres in additional Member States without triggering a review or a repetition of the scientific assessment carried out in relation to the conduct of the trial in the initial Member States.

- All SUSAR reporting should be centralised through reporting to the Eudravigilance database only.

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

Yes, the above proposed solution would make a significant different to the industry's access to the clinical trials "market" in other Member States

3. Can the impact be monetised?

Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1. Be as specific as you can although order of magnitude is also useful

What is the nature of the costs accrued? Eg. Transaction costs; Opportunity costs; Administrative burden

The potential costs would be **significant if <u>all operators</u> are taken into consideration** (including both industry and non-industry clinical trial sponsors, as well as national competent authorities and ethics committees). Such stakeholder-wide costs would of course be difficult to monetise though, given the diversity of types and sizes of organisations, operating models and procedures, numbers of clinical trials, etc.

Arguably **of greater concern** than the costs are the **risks** associated with the complexity, number of tasks performed, the inability to reuse documentation, and multiple or lack of SUSAR reporting, as have been described in Box 1 above.

GSK: Variations Regulation – Non-uniform implementation by EU Member States

1. What is the regulatory issue affecting your business?

Please identify the specific EU regulation affecting your business

Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, such as changes to a manufacturing process, or to a patient information leaflet.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:334:0007:0024:en:PDF

This revision to the Variations Regulation was a key theme for the Commission's 'Better Regulation of Pharmaceuticals' initiative.

The overall objectives for the revision of the Variations Regulations are:

- to make the regulatory framework on changes to medicinal products simpler, clearer and more flexible;
- to provide an overall reduction in administrative burden;
- harmonisation of procedures, requirements and timelines for national authorisations;
- accommodation of new ICH quality concepts;
- without compromising human safety.

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else

On 12 December 2008, "Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products" was published in the Official Journal of the European Union (OJ L 334 p. 7). This Regulation took effect from 1st January 2010, and was implemented for products authorised via the Centralised, Mutual Recognition and Decentralised procedures from that date. However, the legal text mandating the application of the new rules to national variations, in particular the ultimate deadline for implementation, has not yet been finalised.

EU level

Some Member States (including the UK and several Nordic countries) have voluntarily implemented the new regulation for their national variations (to the extent that these do not require that other Member States adopt the same approach) at the same time as for products authorised using European procedures, i.e. from January 2010. Other Member States (including Greece and Romania) have voluntarily implemented the new regulation for their national variations from January2011.

However, some Member States (including France and Poland) have still to implement the new regulation for their national variations, and may not implement until a date for mandatory implementation for national variations has been defined in the final Comitology text (date to be defined, but potentially as late as 2013).

As a consequence, there is a potential for an extended implementation "window" for application of the new regulation to national variations across the different EU Member States.

The breadth of this window will depend on the date agreed in the Comitology text by EU legislators for final mandatory implementation of the new regulation to national variations.

UK level

The MHRA took a very welcome, proactive and leadership approach to implementation of the new rules. They immediately applied the Variations Regulation (EC/1234/2008) to variations to marketing authorisations covered by European procedures from 1st January 2010; and has also applied it to purely national variation applications from that date also.

What business activities are affected?

All functions in GSK involved with the generation of data and documentation to support variations, principally Manufacturing and central Regulatory Affairs groups, and regulatory departments based locally in the Member States who are responsible for submitting national variations

How recurrent / common is the problem?

Ongoing

How do you currently deal with the situation?

GSK needs to manage different internal processes to support different regulatory requirements for national variations in Europe until all Member States have fully implemented the new Variations regulation, at the national level.

The major concern is that this would need to be managed over an extended period of time.

Is your experience of the regulation/s in other Member States different?

See response under *EU Level* above.

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

In order to obtain the full benefits of the new EU Variations Regulations as early as possible, and to minimise the inefficiencies arising from managing national variations in different ways, GSK believes that the implementation "window" for completing the application of the new rules in all Member States should be as narrow as possible, and ideally should be no longer than 30 months in duration (i.e. January 2010 - June 2012).

Consequently, we propose that the final date for mandatory implementation by the Member States of the new rules for national variations (as to be defined in the Comitology text to be drafted by the Commission) should at the latest be set as June 2012.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

Yes – in order to realise the full benefits of the Regulation, the Commission should introduce the final Comitology text which makes implementation at the national level mandatory and sets a clear timetable for this.

According to the Commission's DG Health and Consumers Management Plan 2011 and beyond, one of the main policy outputs for 2011 will be a Revision of Commission regulation on variations: adaptation to cover national variations. However there is a lack of transparency around this work and the timetable for the availability of the final Comitology text is not known.

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

No - the UK is one of the EU Member States, who is taking the lead on this.

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

Yes (see above).

3. Can the impact be monetised?

Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1. Be as specific as you can although order of magnitude is also useful

What is the nature of the costs accrued? E.g. Transaction costs; Opportunity costs; Administrative burden

The need to manage different internal processes to support different regulatory requirements for national variations in Europe results in additional administrative burden which increases resource requirements and therefore cost.

It is difficult to monetise the full impact of this regulatory issue. However, we have identified **2 real-life examples** which clearly illustrate the impact of delayed approvals of variations across EU member states in terms of:

1) Additional resources consumed or costs incurred by the Company;
2) Potential for disruption to the continuous supply of a medically critical product;
3) Delays in implementing changes which have the potential to improve product quality.

Example 1

Product A was previously categorised as a chemical substance but recently due to changes in the European Pharmacopeia, this product was re-categorised as Biological in the EU. The result of this re-categorisation was that all changes to starting materials, intermediates or drug substances will be treated as Type II variations. There is significant divergence of requirements for these types of changes from individual EU national authorities and some authorities within the EU have lengthy and inconsistent approval times which can result in a planned change being unable to be fully implemented across the EU until all approvals have been received. The consequence of these lengthy and inconsistent approval times has implications for securing supply to all EU markets. In addition the inconsistency of approval times by some EU Regulatory authorities makes it very difficult to plan future supply with any confidence.

A business risk assessment on the impact of divergent requirements, lengthy and inconsistent approvals times for the product in question estimated that the **cost to the business could be as much as $100 Million**.

Example 2

An API source transfer is ongoing for a medically critical product. The API is used in respiratory devices, tablets, syrups, solutions for injection/infusion and solutions for nebulisation. Approval for the first EU submissions (Type IB) were approved in 60 days; however the **change took significantly longer in other markets** such as Poland (still not approved for some dose forms after 10 months + 60 days to obtain an EU approval letter from another market in order to submit in Poland), Cyprus (9

months + 60 days to obtain an EU approval letter from another market in order to submit in Cyprus), Greece (8 months) and France (9 months).

These delays in approval have **delayed market switches** to the API from the new supplier and have had an **impact** not only on the site involved in the manufacture of the API but also **all 20 sites involved in the manufacture of the Drug Product**. The delays have impacted negatively on volume driven cost of goods reduction initiatives and have also necessitated purchases of additional quantities of imported API from a 3rd party source at the expense of product manufactured at GSK primary sites in the UK. Partial source switches have had to be implemented in some cases, **increasing the complexity and cost of inventory management and control at secondary sites**.

GSK: Facilitating Innovation and New Technology in Pharmaceutical Manufacturing

1. What is the regulatory issue affecting your business?

Please identify the specific EU regulation affecting your business

The innovation capacity and pace of the pharmaceutical industry is determined, to a great extent, by the external regulatory environment in which it operates. The legislative framework for medicines in Europe is very complex, and there a number of EU regulations, directives and quality guidelines, as well as ICH quality guidelines, which directly impact pharmaceutical development and manufacturing .

Whilst there are a number of EU regulatory procedures that support Innovation initiatives, these have not necessarily been developed for facilitating or promoting the introduction of innovative new technologies in pharmaceutical manufacturing, and are not optimum.

The primary legislation is **Directive 2001/83/EC** relating to medicinal products for human use, amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC. Article 23 of Directive 2001/83/EC requires that marketing authorization holders must, in respect of the methods of manufacture and control), take account of "scientific and technical progress" and introduce any changes that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods

The integrated implementation of the ICH Q8, Q9 and Q10 guidelines provide a systematic, modern risk- and science- based approach to pharmaceutical manufacturing and development, and enable companies to move towards a new quality paradigm. This provides a platform for introducing innovative manufacturing technologies e.g. Continuous processing, innovative analytical technologies, as well as alternative approaches to traditional process validation e.g. continuous process verification.

Describe the current situation, including whether the regulatory problem stems from the European regulation/directive itself, UK implementation, enforcement or something else

The **development of new technologies and innovative approaches is accelerating at significant pace**. This is driven advances in manufacturing science and led by other industries including the Oil / Gas, Semi- Conductor and Food industries. The adoption of these technological advances in the pharmaceutical industry will **support enhancements in patient benefit, access to medicines, product quality, manufacturing control and efficiency, supply chain efficiency and security, and sustainability**.

A **significant hurdle to the adoption of these technologies** in the pharmaceutical industry is that the **EU regulations and guidelines do not always keep pace with these rapid developments in manufacturing science**. As a consequence, a new technology and/or or innovative approach may need be introduced, where regulatory

provisions do not exist, or have not been sufficiently developed. This can often resulting in a competent authority taking a **risk adverse approach thereby creating a regulatory barrier, and this could stifle innovation**.

There may be situations where companies are at the leading edge of introducing innovation approaches to pharmaceutical manufacturing, and there may be a **considerable lag time** before assessors become aware and understand these new technologies. Furthermore, the **large number of competent authorities** involved in assessing marketing applications (including the EMA and 27 EU member states) and applying new legislation and/or guidelines **compounds the issue**, as training needs to be rolled out to assessors in all these agencies to raise awareness.

This does not provide an ideal platform to facilitate a harmonised transparent and evenly implemented regulatory framework to support the introduction of innovative technologies. This also has the potential to delay, stifle or even prevent innovation.

What business activities are affected?

Product Development and Manufacturing functions in GSK involved with the development and manufacture of APIs and medicinal products, as well as Regulatory Affairs groups responsible for supporting regulatory submissions and approvals.

How recurrent / common is the problem?

This is an ongoing and common problem. The **impact of this issue will become even more pronounced** as the need to adopt innovative technologies will increase to ensure affordability and access to medicines in global markets, particularly the emerging markets like Brazil, Russia, India and China.

How do you currently deal with the situation?

It is managed on case by case basis, but this is not cost or time efficient. Furthermore the approach is reactive and not proactive.

Is your experience of the regulation/s in other Member States different?

There a number of Member States, including the UK, who have a more enlightened and pragmatic approach to accepting innovative manufacturing technologies. Whilst the update of innovative technologies by some Member States is more problematic.

<u>Ireland – Irish Medicines Board (IMB)</u>

The IMB have been very progressive in the last 5 years in promoting the adoption of innovative manufacturing technologies. They have proactively approached pharmaceutical companies and asked for early engagement / dialogue so that the IMB could better understand the technology and benefit to patient and product. This has resulted in more educated inspectors and timely approval of regulatory changes for innovative manufacturing technology.

USA – FDA

The FDA has led the regulatory community and industry in promoting the adoption of innovative manufacturing technology and science based approaches. All other regulatory agencies have followed the lead set up by the FDA. They have introduced numerous pilot programmes to promote engagement and dialogue in the selection and use of innovative technologies.

2. What is the proposed solution?

What changes to your experience of the regulation/s identified in Box 1 make a positive difference to your business?

General Considerations

- As regulations and guidelines do not always keep up with the pace of scientific and technical developments, there needs to be a greater recognition and acceptance that science should drive innovation and regulations need to follow.
- There is opportunity to be more proactive in this regard with industry working with the regulators to educate and look at future trends in manufacturing science.
- Scientific Dialogue

Improved dialogue between industry and regulators, particularly during the identification and development phase, would help to raise awareness and understanding of innovative technologies, and would reduce requests for additional data and regulatory questions following submission. With the goal of increasing predictability of outcomes for marketing authorisation applications, the following should be considered:

  - Modification of existing procedures or creation of new procedures to facilitate early scientific dialogue on the introduction of innovative technologies ;
  - increased availability of trained regulators to participate in scientific and technological dialogue at key milestones during product life-cycle;
  - Leading to a regulatory environment that enables effective dialogue between industry and regulators across the product lifecycle, supporting innovation and continuous improvement.

- Increased acceptance by regulatory authorities of innovation approaches to product development and manufacturing , and the benefits this brings to the patient.
- Increased training for reviewers involved in providing advice or assessing submissions containing innovative approaches to pharmaceutical manufacturing.

Potential new mechanisms through which we can facilitate the introduction of innovative technology

- Introducing a specific process for achieving scientific input from EMA on the introduction of innovative technology.
- Organise joint workshops between Industry experts and regulators to discuss advances and trends in innovative technologies and manufacturing approaches.
- Consider developing a specific category within variation guidelines for introduction of innovative technology.
- Consider developing a centralized review and approval process for the introduction of innovative technology.
- Provide an accelerated review process for introduction of innovative technology.
- Increase the mandate (focus) of "Innovation Task Force" to include innovation in manufacturing technology.
- Provide a "pilot window" to support industry gaining more practical experience of a new technology, before implementing new guidance.

Summary

It is essential that there is an enabling regulatory environment that not only is conducive to, but actively encourages and incentivizes innovation in pharmaceutical manufacturing.

Does the proposed solution involve changes to the European legislation itself, implementation in the UK, enforcement, something else – or all of the above?

The proposed solution may involve some changes to the European legislation itself, but it is also about creating a more flexible regulatory mindset.

Does your experience of the regulation/s in another Member State suggest that we can do better in the UK?

There are opportunities for the UK (MHRA) to do better, in terms of promoting innovative technologies more effectively in the UK itself and through the European groups it chairs or leads**.**

Does your experience of the regulation/s in another Member State suggest that their implementation can be improved to aid UK access to markets?

Yes, as above. This is also a significant opportunity for the UK to be seen as the prime location for the rapid development and deployment of innovative technology to enhance patient benefit.

3. Can the impact be monetised?

Estimate, if possible, the cost to your business posed by the regulatory issue identified in Box 1. Be as specific as you can although order of magnitude is also useful

It is difficult to quantify the absolute cost to our business. However, by benchmarking the benefits obtained in other industries, where innovative technology has been rapidly adopted, it is clear to see the significant benefits to patients by making them more affordable (by improving manufacturing efficiency and control) and increasing access (by improving product development and supply chain efficiency.

Furthermore, countries in which the regulatory mindset is seen to be proactive and more flexible will be seen as prime locations for future investments in pharmaceutical development and manufacturing

What is the nature of the costs accrued? E.g. Transaction costs; Opportunity costs; Administrative burden

Leads to delays in introducing new technologies which support enhancements in patient benefit, product quality, access to medicines, manufacturing control and efficiency, supply chain efficiency/security, and sustainability.

TRIBEKA

1. **Patents/IP**

Regulatory Issue

There is currently no European single patent and this makes it very difficult for SMEs to file and gain patent protection in Europe. Moreover the European and UK patent offices make efforts to decline any patents that are related to (or even executed in) software and use a wide scope for excluding patent applications on the basis of their being a business model. There is a significant cost to dealing with this and so these conditions discriminate against SMEs and particularly technology based SMEs where much of the UK's innovation is (to be) derived. It is a mistake to further discourage SMEs by the Patent box initiative by tying favourable CGT to UK or European patents.

Example: Tribeka has a US patent with several under review, but we have all but dropped our European patents due to cost and patent office objections.

Proposed solutions

Single European patent

Task patent offices with easing financial burden on SMEs by making efficiencies in the process such as easing the paperwork

Provide clearer (and narrower) definitions of patent areas that are disqualified under business model and software exclusions

Create a framework for favouring innovative solutions with preferential CGT that is not based on UK/European patents

Costs

Actual Costs: £10,000s per patent of actual costs plus £1,000s of internal resource costs, whether granted or not

Opportunity Costs: SMEs may avoid filing patents and use trade secrets instead. This inhibits innovation

Loss of 10% CGT opportunity

Makes VC more difficult to raise

Makes the USA a potentially easier and more lucrative marketplace

2. **VAT and Domestic Supply**

Regulatory Issue

There is an issue with VAT and domestic supply across Europe. We have experienced this selling goods as a UK company to a German company.

Example: Where some of the equipment is shipped directly from Germany, German VAT is payable on the domestic German shipped goods even though the complete order is between a UK and a German company. The goods would need to be shipped out of Germany and back in to avoid this (not very eco friendly!). Companies have to have registered for VAT in Germany before the delivery otherwise VAT is not reclaimable.

Proposed solutions

Review VAT rules surrounding domestic supply for companies trading across Europe

Allow VAT registration after supply

Make companies aware of the potential issue

Costs

Actual Costs: Loss of VAT reclaim on transactions

Transport and delivery of equipment to outside the member state for re-import

Opportunity Costs: Difficulty of ordering equipment locally to support local businesses

3. EU Agency Regulations

Regulatory Issue

Agents can be very useful for SMEs and particularly innovative SMEs with new products entering new markets however EU Agency regulations are extremely weighted in favour of Agents disincentivising SMEs from using them (even informally).

Example: (i) Agents are entitled to damages even if the agency agreement has simply expired (ii) the definition of an agent is very wide and includes parties without contract (iii) potential damages are very high.

Proposed solutions

Review agency regulations and exempt SMEs

Allow contract to overrule legislation

Narrow scope of agency regulations for informal arrangements

Make companies aware of the potential issue

Costs

Actual Costs: Excessive damages for companies

Opportunity Costs: Avoidance of agents slowing down export opportunities

Agents inhibiting additional opportunities for companies in member states

4. Regulations and Changing Regulations

Regulatory Issue

These are constantly changing, European and UK issues which are particularly onerous for SMEs and fast growing companies.

Example: (i) the requirement to keep CVs of everyone who applies for a role (ii) being required to respond within 28 days to anyone, including those not even being called to interview or following a telephone call, for complete answers on all applicants to prove there is no discrimination, (iii) the continuous extension of employment laws such as new paternity leave, the proposal to include space for breast feeding etc, (iv) the no win, no fee culture.

Proposed solutions

Limit awards to a percentage of turnover of the company

Limit the use of no win, no fee actions against SMEs

Costs

Actual Costs: Excessive damages for companies sometimes forcing bankruptcy

Costs of defending against speculative claims

Costs of micro managing the recruitment process and employment matters, keeping all paperwork and responding to speculative claims

Opportunity Costs: Limits SMEs from employing staff and especially from recruiting out of work staff

The difficulty in getting or giving references

5. Single Market Act Proposal

Regulatory Issue

Proposal No 6: The Commission will propose a legislative reform of the standardisation framework in 2011 to make standard-setting procedures more effective, efficient and inclusive and to extend the scope of the procedures from goods to services.

Concern about using standards to override legitimate patents and IP. This will particularly affect SMEs.

Proposed solutions

Prevent standard setting overriding patents/IP without patent/IP holders approval

Costs

Actual Costs: Loss of patent/IP

Opportunity Costs: SMEs and other companies may avoid filing patents and use trade secrets instead. This inhibits innovations

Regulatory Issue

Proposal No 10: Before 2012, the Commission will look into the feasibility of an initiative on the Ecological Footprint of Products to address the issue of the environmental impact of products, including carbon emissions. The initiative will explore possibilities for establishing a common European methodology to assess and label them.

This could have greater impact on SMEs and innovative SMEs and might hinder the development and take-up of innovative products and services.

Proposed solutions

Exclude SMEs and companies trying innovative solutions from SMEs from this proposal

Costs

Opportunity Costs: Innovation will occur and be developed in other countries

Regulatory Issue

Proposal No 12: The Commission will adopt an action plan for improving SME access to capital markets in 2011. This will include measures to make investors more aware of SMEs, to develop an efficient stock exchanges network or specific regulated markets focussing on SMEs and to make listing and disclosure requirements more adapted to SMEs.

Finance is service industry and follows the market.

Proposed solutions

Improve the benefits for Business Angels

Look at the success of Israel in quickly creating an innovation mindset and marketplace; and becoming the VC "capital of the world" (per capita)

Costs

Opportunity Costs: Innovation will occur in other countries

Regulatory Issue

Proposal No 38: The Commission will launch a public consultation (Green Paper) on corporate governance. It will also launch a public consultation on possible ways to improve the transparency of information provided by businesses on social and environmental matters and respect for human rights. These consultations could lead to legislative initiatives.

Proposed solutions

Exclude SMEs

Costs

Actual Costs: Increased burdens and costs for SMEs

Costs of micro managing the processes, keeping all paperwork and responding to speculative claims

Opportunity Costs: Inhibits product expansion and export opportunities

Regulatory Issue

Proposal No 39: In 2011 the Commission will draw up a multiannual action plan for the development of European market surveillance. In addition, in relation to the customs services and the market surveillance authorities of the Member States, the Commission will draw up guidelines for customs controls in the area of product safety in 2011. The Commission will also propose a revision of the general product safety Directive in order to ensure a coherent and effective framework for the safety of consumer goods in the EU.

This could have greater impact on SMEs and innovative SMEs and might hinder the development and take-up of innovative products and services.

Proposed solutions

Exclude SMEs and companies trying innovative solutions from SMEs

Costs

Opportunity Costs: Innovation will occur in other countries

TESCO: Low-alcohol wine

Tesco would like to meet the increasing consumer demand for low alcohol wines as part of its efforts to encourage responsible drinking. Currently within the EU, low alcohol wine may (with a few exceptions) generally only be described as wine if its alcohol content meets or exceeds 8.5 per cent by volume. Tesco argues this means that consumers are not being given the choice that is afforded by recent advances in wine production technology. This regulatory prohibition is limiting consumers who wish to choose low alcohol wines for health reasons.

This publication is also available on our website at www.bis.gov.uk

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