



Business Regulation Team Scoping Report 2005



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Section 1: Summary

The aim of the Business Regulation Team, part of the Regulatory Impact Unit in the Cabinet Office, is to reduce the burden of existing regulation on the private sector, by engaging directly with the business community, to identify specific areas of concern, and by delivering change through joint action plans agreed with relevant government departments. The team was set up in 2001, as a result of discussions between the Prime Minister and industry leaders, and is staffed largely by secondees. The purpose of this report is to summarise the work which has been undertaken by the Team, to assess options for its 2005 work programme, and to describe the proposed work programme. The main conclusions are as follows.

- **Environmental services sector.** It is proposed that work on the environmental services sector, which has been one of the three main strands of the Team's 2004 work programme, should continue to be one of the main strands of the Team's work in 2005. The main reasons for proposing this are as follows: (i) there are many regulatory issues in the sector; (ii) many of the issues have links with key government policies (eg on renewable energy, recycling, and the remediation of brownfield sites); and (iii) some of the Team's current initiatives will take some time to come to fruition, and should not be abandoned in mid-stream. Development on brownfield land is the subject of a national target – that 60% of additional housing should be on previously developed land.
- **Logistics sector.** It is proposed that the logistics sector should form one of the main

strands of the Team's work in 2005. Reasons for proposing this include the following: (i) there is a significant demand from business to look at issues in this area, following the whole supply chain, rather than a single step in the process; (ii) the logistics sector is a major contributor to GDP; and (iii) it builds on, and significantly expands, the work on the transport sector carried out by the Team in 2004.

- **Pharmaceuticals sector.** It is proposed that the pharmaceuticals sector should form one of the main strands of the Team's work in 2005. The main reasons for proposing this include the following: (i) it is a major contributor to GDP with strong growth prospects; (ii) the sector is extensively regulated and there is a risk that activities such as R&D will move elsewhere if the regulatory regime is disproportionate; and (iii) organisations in the sector are keen for the Team to become involved.
- **Other work.** It is proposed that the Team also undertakes certain other work in 2005, relating to the following areas: (i) follow-up work in the **construction sector** (eg on the review of the adjudication and payment provisions of the Construction Act); (ii) follow-up work in the **marine industry**; (iii) work on three main areas of regulation of the **food sector**: (a) establishment of an industry-government group on regulation; (b) traceability; (c) disposal of animal by-product waste; and (iv) work to improve the planning/consent processes for **wind farms**.

Section 2: Introduction

The Regulatory Impact Unit

The Regulatory Impact Unit (RIU) within the Cabinet Office works with other government departments, agencies and regulators, to help ensure regulations are fair and effective, and that all new and existing regulation is necessary. New regulations should comply with the principles of better regulation and impose the minimum burden. The RIU therefore plays a role in helping to reduce bureaucracy and cut red tape.

The Business Regulation Team

In early 2001, the Prime Minister met representatives of a number of the UK's major corporations, to discuss their views about red tape and the burden of regulation on business. In response to their concerns, the Prime Minister invited each of the companies to nominate an individual to join the RIU on secondment. As a direct result of this initiative, the Business Regulation Team (BRT or the Team) was established in September 2001. The aim of the BRT is to reduce the burden of existing regulation on the private sector by engaging directly with the business community to identify specific areas of concern, and by delivering change through joint action plans agreed with relevant government departments. The majority of the Team are secondees and half the Team members are on secondment from the private sector.

Purpose of this report

The purpose of this report is to summarise the work which has been undertaken by the BRT, to assess options for its 2005 work programme and to describe the proposed work programme.

Scope of BRT's work to date

Since the Team was established in September 2001, it has undertaken work in the following sectors:

- 2002: Retail sector and chemicals sector.
- 2003: Ports, transport (vehicle standards), food and drink, pharmaceuticals and bio-pesticides. The work programme in this year also covered statistical reporting.
- 2004: Construction, environmental services and transport sectors.

The work undertaken each year by the BRT is described in its End of Year Reports (see Annex A).

Section 3: Approach

The approach to scoping the BRT's work programme for 2005 has followed three main lines of enquiry.

- Evolutionary (building on the 2004 work programme)
- Structured
- Business-led.

Evolutionary approach

The evolutionary approach has been to build on the experience gained in the 2004 work programme which has focused on construction, environmental services and transport.

Structured approach

The structured approach to identifying possible sectors for regulatory review in 2005 has involved analysing information on the relative weightings, in the economy, of individual sectors. This information has been obtained from two main sources.

- *Sector weightings based on Gross Domestic Product (GDP)*. The first set of information relates to the contribution of each sector to the total UK GDP. This information includes industries in both the public sector (eg public administration and defence) and private sector (eg financial intermediation). The information is tabulated in Annex B.
- *Sector weightings based on the FTSE All-Share Index*. The second set of information relates to the market capitalisation of those companies in the sector which are included

in the FTSE All-Share Index to the market capitalisation of all companies which are included in the FTSE All-Share Index. This information relates only to the private sector. The information is tabulated in Annex C.

This information has been reviewed by the team. It does not necessarily follow that the fact that the BRT has undertaken work in a particular sector rules out that sector for further work. For example, the work undertaken in 2002 in the chemicals sector focused on operational enforcement. There may be other regulatory issues in the sector which would merit further work in the sector.

Business-led approach

The business-led approach has been to engage with business and other organisations with a view to identifying suitable sectors for review in 2005. Meetings have been held with the Confederation of British Industry, the Federation of Small Businesses, the Institute of Directors and the Trade Association Forum (TAF). Meetings have also been held with a small number of trade associations following contacts made through TAF. A list of organisations and reports which contributed to the Scoping Study is at Annex A.

Other considerations affecting the choice of sectors

A number of other considerations may affect the choice of sectors or topics for regulatory review. Such factors include the following. One factor is the need to avoid duplication with the work of other bodies, such as the work of the Prime Minister's Panel for Regulatory Accountability and

the Better Regulation Task Force. Another factor is the need to avoid potential conflicts of interest. The private sector members of the Team are currently drawn from the banking, defence and telecoms sectors. These members are not permitted to work in their own sectors, but this does not rule out other members of the Team working in those sectors.

Section 4: Environmental services

Work on environmental services in 2004

The environmental services sector has been one of the three main study areas in the BRT's 2004 programme. This work has identified a large number of regulatory issues affecting the sector. These fall into a number of main areas: (i) renewable and sustainable energy; (ii) waste management and recycling; and (iii) brownfield site remediation. In addition, the Team is addressing other issues affecting the sector such as state aid or the legal framework of the Broads Authority.

Environmental services – current issues

The work on the environmental services sector in 2004 has identified many regulatory issues affecting the sector. As at the end of September 2004, some 19 topics had been identified, some of which contained several regulatory issues. Some examples are given below, for each of the main areas of work.

Renewable and sustainable energy

The Team is working on a number of live issues in the renewable and sustainable energy sub-sector. Examples include the following.

- *Hydropower.* The Team is working with hydropower organisations (primarily represented through the British Hydropower Association) on issues relating to the complexity of the regulatory framework, in particular the process of gaining approvals for new hydropower developments.
- *Pre-blending.* The government's policy on sustainable and renewable fuel is manifest in the Renewable Obligation (RO), introduced in April 2002. The RO places an obligation on licenced electricity suppliers to source a specified and increasing proportion of electricity from renewable sources. Renewable Obligation Certificates (ROCs) are issued to accredited generators for eligible renewable electricity generated within the UK and supplied to GB customers, and can be traded. The RO is the key policy mechanism which the Government is using to meet our aim for renewables to supply 10% of UK electricity in 2010, subject to the costs being acceptable to the consumer. The RO allows the co-firing of fuel blended from a mix of fossil and non-fossil origins. ROCs are issued on the basis of generators meeting a fixed blend-mix. For a variety of economic and environmental reasons, the generators would like to pre-blend the fuels prior to delivery to the generating station, usually at the port of entry. However, Ofgem will only currently allow pre-blending at the generating station. BRT is seeking to resolve the issue.
- *Renewables rating system.* The Valuations Office has been reviewing the business rate for the renewable energy industries. It is likely that the outcome will see a significant increase in rates to the extent that some businesses may struggle to make ends meet. Industry is seeking to reduce the impact of these changes by excluding the uncertain income derived from ROCs. The BRT is working with all stakeholders to seek a resolution of this issue.

Recycling and waste management

The Team is working on a number of live issues in the area of recycling and waste management. An example is used cooking oil (UCO). There are four main consumers of UCO: the incineration community, the blenders for foodstuffs, the oleochemical industry and the biodiesel community. Legislation came into force on 1 November 2004 which prevents the blenders from using UCO in foodstuffs. Consequently, there is the potential for a serious disposal problem. The BRT is in discussion with industry and the regulators, in establishing alternatives to conventional regulation, that would both avoid the fly-tipping of 'homeless' UCO and provide an audit scheme to establish 'traceability'.

Brownfield site remediation

The topic of brownfield site remediation is one for which Government has set targets. There is a national target for 60% of additional housing to be on previously developed land. This is set out in Planning Policy Guidance 3 (Housing) of March 2000, issued by the Office of the Deputy Prime Minister, which states (Paragraph 23): "The national target is that by 2008, 60% of additional housing should be provided on previously developed land and through the conversion of existing buildings. Each region will propose its own recycling target to be set in RPG [Regional Planning Guidance], which should contribute to achieving the national target."

The Team is working on a number of live issues in the area of brownfield site remediation. Examples include the following.

- *Simplified permitting.* BRT has helped to establish, and is chairing, a joint industry-government team (Remediation Licensing Task Force) which is charged with the delivery of a simplified permitting system for the brownfield remediation industry.
- *Soil guideline values (SGVs).* The land remediation industry is required, under UK regulation, to provide evidence of soil purity before a given site can be regarded as 'clean'. The use of SGVs is part of this process but only a small proportion of the 90 SGVs is available. BRT is working with

interested parties in government and industry in identifying and removing the barriers to the production of this data.

The case to continue work on environmental services in 2005

In the light of the experience of this work, it is considered by the Team that there is a strong case for continuing the work on environmental services throughout 2005 as a main element of the 2005 work programme. The main reasons in favour of continuing to work on environmental services in 2005 include the following.

The environmental services sector is a relatively young and evolving sector. It is also a sector which attracts the attention of both the voting public and consequently government departments. Many of the 'headline political issues' over the past twelve months – renewable and sustainable energy, brownfield site remediation and the associated housing targets, and the all-pervasive issue of recycling and waste management in its various guises – are spawned from the Environmental Services Sector. In the 'Mid-corporate growth survey', published by Grant Thornton and CBI in November 2004, 38% of respondents considered that regulations relating to environmental issues required excessive input. The environmental services sector is a rich seam of potentially 'high-impact' regulatory issues.

The BRT has had a particularly successful year in addressing many of these issues and in doing so has established good working relationships with all stakeholders from both the public and private sectors. Many of the initiatives, which have been conceived to address the identified problems, are now at a critical stage in their development, and to abandon them would result in failure.

Accordingly, an expectation amongst all stakeholders regarding the role of the BRT has been created. Failure to meet this expectation would undoubtedly be perceived very negatively by both government departments and the private sector.

Conversely, to continue in the current vein would be to garner ever-growing support and

recognition from the said stakeholders and would do much to enhance the government's reputation for addressing the regulatory burden in this high profile and important market. Equally importantly, the BRT and Cabinet Office will make a valuable contribution to the promotion of green issues that will make a genuinely positive contribution to resolving many of the potential problems associated with energy supply, transport and waste management.

Conclusion – environmental services

It is proposed that work on the environmental services sector which has been one of the three main strands of the Team's 2004 work programme, should continue to be one of the main strands of the Team's work in 2005. The main reasons for proposing this are as follows: (i) there are many regulatory issues in the sector; (ii) many of the issues have links with key government policies (eg on renewable energy, recycling, and the remediation of brownfield sites); and (iii) some of the team's current initiatives will take some time to come to fruition and should not be abandoned in mid-stream. Development on brownfield land is the subject of a national target – that 60% of additional housing should be on previously developed land.

Section 5: Logistics

Introduction

It is proposed that, building on the Team's work in the transport sector in 2004, the logistics sector should be one of the main strands of the Team's work in 2005. The reasons for proposing this are described below.

Economic significance of the logistics sector

The logistics sector is tasked with ensuring that the right products reach the right place in the right quantity at the right time to satisfy customer demand. The UK logistics sector employs over 1.7 million people in over 63,000 companies and is directly worth about £55bn to UK GDP. The sector encompasses freight transport, storage and warehousing, courier services, air and rail freight, freight on inland and coastal water transport. It also includes the import and export trade. According to HM Customs & Excise statistics, in 1999, the number of VAT-registered companies involved with importing was approximately 91,000. The value of goods imported was £110bn. The number of companies involved with exporting was 126,000 and merchandise exports in 1999 came to around £74bn. Most supply chains are served by small logistics businesses who provide specialist technical services. They work within frameworks managed by large logistics firms.

Work in 2004 and live issues

During 2004, the Team has been working on a range of regulatory issues affecting the transport sector, for example, measures to help the vehicle hire sector to operate more efficiently. While a number of successes have been achieved, there are some significant regulatory issues where a longer time horizon is required, ie into 2005. The first of these involves working with government

and industry to look at the potential for relaxing restrictions on deliveries to retail sites (described in more detail later in this chapter), and secondly, working with the plant hire sector to explore with HM Customs & Excise how the regulatory burden associated with the sale of red diesel might be reduced.

Liaison with industry

A series of meetings has been held with industry bodies and with companies in the industry. Organisations with which the team has been in contact include the following:

- *British International Freight Association (BIFA)*. BIFA is the representative body of the freight forwarding sector and comprises over 1,200 companies ranging from multinationals to a large number of SMEs. BIFA members are understood to be responsible for 80% of UK freight forwarding business.
- *British Vehicle Rental and Leasing Association (BVRLA)*. The BVRLA is the trade association representing companies involved in the rental, contract hire and fleet management of cars and commercial vehicles. The association has over 800 members who operate more than 2.3 million vehicles and buy 1 million new cars, vans and trucks every year.
- *Road Haulage Association (RHA)*. The RHA represents around 10,000 vehicle transport companies operating within the hire-and-reward sector of the UK logistics industry. The majority of members are SMEs.
- *Freight Transport Association (FTA)*. The FTA represents the transport interests of

companies moving goods by road, rail, sea and air. FTA members operate over 200,000 goods vehicles – almost half the UK fleet. In addition, they consign over 90 per cent of the freight moved by rail and over 70 per cent of sea and air freight.

Issues raised by business

Industry has raised a range of logistics issues with the BRT. A brief outline of some of these is given in the following paragraphs. The BRT undertakes a detailed review of issues raised with us prior to deciding upon a final shortlist of issues to be addressed as part of our annual work programme. The BRT has not undertaken a detailed review of any of the issues raised with us by business, and inclusion of any of the areas mentioned in the following paragraphs in our 2005 Work Programme is subject to the outcome of that detailed review.

Logistics information chain

Streamlining the logistics information chain with respect to the regulation of the export/import (EXIM) trade was flagged up to us. Businesses are interested in exploring with Government the potential for moving to a “single window” information portal providing EXIM businesses with web-enabled access to relevant Government IT systems regulating the EXIM trade. This portal would collect, collate, process and provide all the information required for EXIM trade facilitation by both industry and Government.

Vehicle licensing

Businesses feel that the current system for vehicle licensing could be improved further, as it still involves a significant amount of paperwork for operators. They feel that more could be done to simplify and modernise the system which would bring considerable cost benefits (in paperwork savings) to SME vehicle operators. The BRT plans to seek further information from business about the level of costs imposed on them by the present arrangements.

Business has suggested that the administrative burden connected to annual vehicle licensing could be reduced. They feel that multi-year vehicle excise licences could deliver significant regulatory cost savings for business. The BRT

plans to seek further detailed information from industry about their proposal and the basis for calculating the regulatory cost savings that may arise.

Industry would also like the multiple payment channels for vehicle licences to be simplified into one payment channel. They have suggested that this single payment channel could be the local Post Office. Again, the BRT plans to seek further detailed information from industry about their proposal.

Issue to be carried forward from 2004 into 2005 – delivery curfews

Work on regulation of the transport sector has been one of the three main strands of the BRT’s work programme in 2004. This work has covered a range of issues as described in the Team’s End of Year Report. One of the main issues tackled in the 2004 work programme was the topic of delivery curfews. It is proposed to carry this issue forward into the 2005 work programme for the reasons described below.

Issue

Delivery restrictions constrain delivery of goods to retail sites during night-time hours. These restrictions are intended primarily to minimise noise nuisance for nearby residential areas. Retailers and logistics companies say that delivery curfews increase their operational costs. If all restrictions were removed, Safeway estimate their fleet could be reduced by 20%, FTA suggests that the UK lorry fleet could be cut by 21,000 and growth in goods vehicle traffic cut by more than 50%. Retail and logistics industries are keen to explore relaxation of curfews and to discuss with Government the potential for moving local policy towards presumption against a complete ban on night-time deliveries.

Economic significance: retail

UK retail sales approximately £236bn in 2003; some 188,600 VAT-registered retail businesses in UK operating in 311,000 retail outlets; retail industry employed over 3 million people as at end of 2003 (roughly 10% of total UK workforce) – all data from Office for National Statistics.

Objectives

The objectives of the work on delivery curfews are as follows.

- To develop joint industry/government “best practice” guidance, incorporating material from central government on planning, noise abatement and traffic policy, from local government on complexities of local planning systems including the planning appeals process, and from retailers on best practices in handling deliveries – guidance will become the benchmark for all parties.
- To use demonstration or “proof of concept” projects (retailers, logistics companies and local authorities working together to test relaxation of curfews in defined area) as a lever, to take forward wider moves to relax curfews, while taking into account concerns of local residents.

These objectives have been agreed provisionally, subject to the retail and logistics industries providing evidence to demonstrate that the measures under consideration will deliver benefits for local residents as well as for industry.

Progress to date

The first meeting of a joint industry/government group on delivery curfews was held on 16 September 2004. Feedback from industry is being gathered to develop the case for the preparation of “best practice” guidance.

Conclusion – logistics

It is proposed that the logistics sector should form one of the main strands of the Team’s work in 2005. Reasons for proposing this include the following: (i) there is a significant demand from business to look at issues in this area, following the whole supply chain, rather than a single step in the process; (ii) the logistics sector is a major contributor to GDP; and (iii) it builds on, and significantly expands, the work on the transport sector carried out by the Team in 2004.

Section 6: Pharmaceuticals

Introduction

The pharmaceuticals sector is one of the largest commercial sectors of the UK economy. Measured in terms of its weighting in the FTSE All-Share index, the pharmaceuticals and biotechnology sector represents around 9% of the total for all commercial sectors. This puts it in fourth place in the sector weightings, behind banks, oil & gas and telecoms. Information on these sector weightings is an Annex C.

Economic significance of the pharmaceuticals sector

Some key figures relating to the pharmaceuticals sector include the following.

- *Exports.* Pharmaceutical industry exports in 2002 were around £10 billion, creating a trade surplus of around £2.59 billion.
- *Research.* The industry invested around £3.2 billion in UK research and development in 2001 – nearly £9 million every day.
- *Employment.* The pharmaceutical industry employs around 65,000 people and generates some 250,000 jobs in related industries.

Government's interest in the sector

The importance of the pharmaceuticals sector to the UK economy is recognised by Government. For example, writing in the Final Report (March 2001) of the Pharmaceutical Industry Competitiveness Task Force, the Prime Minister wrote: "A successful pharmaceutical industry is a prime example of what is needed in a successful knowledge economy. The UK's pharmaceutical industry has an outstanding tradition and has

contributed very substantially to our economy and to the welfare of our citizens." The Prime Minister included a further reference to the sector in his speech to the CBI in Birmingham on 18 October 2004 in which he said: "We have world beating companies – our pharmaceutical industry exports more by value than any of its foreign competitors".

Previous BRT involvement

BRT had some involvement with the pharmaceuticals sector in the course of its 2003 work programme. Initiatives with which the BRT was involved were as follows:

- Simplification of the process by which pharmaceutical companies apply for a licence to import embryos, semen and ova for research purposes
- Simplification of the quarantine requirements for live animals imported for research purposes
- Removal of the requirement that drug companies employing veterinary surgeons engaged in research to be licensed to possess controlled drugs for animal welfare purposes.

Liaison with industry

A number of meetings have been held with industry bodies and with companies in the industry. Organisations with which the team has been in contact are listed in Annex A.

Issues raised by business

A brief description of each of the key issues raised by industry is given in the following

paragraphs. The inclusion of an issue in this list does not necessarily mean that it will be included in the shortlist of issues which will be selected for more detailed review. Similarly, the exclusion of an issue from the list should not be interpreted to mean that it will not be covered. The selection of issues for further review is subject to the outcome of further work, as described below.

Clinical Trials Directive

A number of organisations have expressed concerns about the impact of the EU Clinical Trials Directive. The Directive (2001/20/EC, adopted on 4 April 2001) came into force on 1 May 2004. The Directive concerns “the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use”. Some of the concerns relate to the future of publicly funded clinical trials in Europe.

Control of Entry Regulations 1987

An issue relating to the Control of Entry Regulations 1987 has been raised. On 17 January 2003, the Office of Fair Trading (OFT) published its report ‘The control of entry regulations and retail pharmacy services in the UK’. It recommended abolition of the current restrictions on NHS pharmacy applications, known as “control of entry”. On 17 July 2003, the Government published its response to the report for England, in which it announced its intention to move cautiously in the direction recommended by the OFT. A further statement was issued by the Department of Health on 18 August 2004 on the subject of implementation of the Government response to the OFT report. One organisation has expressed concern that the impact of the proposed exemptions – particularly the one-stop primary care centres and the 15,000 sq metre exemptions – is likely to be difficult to predict.

Data exclusivity and the ten-year rule

The issue of data exclusivity and the ten-year rule has been raised. Currently UK companies have 10 year data exclusivity. This compares with six years in the EU and five years in the US. One organisation considers that there is a case for a

reduction in the UK to six years, and a ban on the practice of pre-patent licence withdrawal and product substitution.

General Practitioner software

The issue of General Practitioner (GP) software has been raised. According to one organisation, the issue, in summary, is that computer programs used by GPs may include information about branded drugs without reference to generic substitutes. The organisation which raised this issue considers that this is likely to increase the cost to the NHS.

Generic substitution

The issue of generic substitution has been raised. The issue, as described by one organisation, is as follows. Where generic substitution is allowed – as it is in hospitals in the UK – pharmacists may dispense a generic medicine when the doctor has prescribed the original brand to which the generic is equivalent. Generic substitution is not allowed in community pharmacy in the UK. Successive Governments have sought to promote the greater use of generic medicines using various measures. As a result of these measures, 71% of all NHS prescriptions are written generically and 52% are dispensed generically. The levels of generic prescribing have increased steadily. However, there is a question whether Government could or should do more to promote a further increase in the use of generic medicines.

NHS drug tariff

The issue of the NHS drug tariff has been raised. One organisation describes the issue as follows. Retail pharmacists acting as contractors to the NHS are reimbursed by the NHS for the medicines they dispense against NHS prescriptions. In the case of generic medicines, the reimbursement price is fixed by the generic pricing mechanism. The Drug Tariff is produced by the NHS monthly, at a substantial cost, and is based upon a basket of prices for specific products offered by three manufacturers and two wholesalers. Branded products do not fall within the generic pricing mechanism but are priced freely by their manufacturers. In the view of the organisation which raised this, the current system has a number of disadvantages and could be simplified yielding benefits to the NHS.

NHS procurement of pharmaceuticals

An issue relating to NHS procurement of pharmaceuticals has been raised. Under the Government's ongoing efficiency review, the Department of Health, operating through the NHS Purchasing and Supply Agency (PASA), has introduced a system of 'National Annual Contracts Sourcing', for the purchase of NHS pharmaceuticals under PASA's 'Supply Chain Excellence' Programme. One organisation is concerned that a system of annual tendering for products could have a number of negative consequences, eg an increase in manufacturers' business risk and difficulties with the shelf-life of products like vaccines.

Animals scientific procedures

Issues relating to the relation of animals scientific procedures under the Animals (Scientific Procedures) Act 1986 have been raised. The principal issue relates to the complexity of the procedures relating to the Act. One of the organisations which raised this expressed the view that the process of obtaining a project licence, to conduct research using animals in the UK, can often be complex and time-consuming. The process remains slow, and for most scientists there is not enough transparency on how the Inspector responsible for their institution makes the cost benefit assessment, and what precise information is required.

Braille medicine labelling

The issue of labelling medicines in Braille has been raised. The amending directive to 2001/83/EC (Directive 2004/27/EC of 31 March 2004) requires that the packaging of a medicinal product be labelled in Braille with the name of the medicine. This amendment is to be put into national law by 30 October 2005. There are some questions to be resolved (eg how the "name" of the product should be interpreted). The view has been expressed that the pharmaceuticals sector faces significant practical problems in implementing the Directive. There is a risk that the costs will be out of proportion to the benefits.

Other issues

A number of other issues have been raised, some of which (eg the Control of Major Accident Hazards Regulations 1999 or the Planning (Hazardous Substances) Act 1990) have an impact on, but are not specific to, the pharmaceuticals sector.

Factors affecting selection of shortlist of issues to be addressed

No decisions have been taken, at this stage, about which of the issues described above might be most appropriate for shortlisting for further review. Further discussions are likely to be needed with interested parties in industry and government before decisions are taken. Relevant factors affecting the choice of issues for the shortlist are likely to include: the potential benefit to industry from resolving the issue; and whether there are good prospects for taking remedial action.

Conclusion – pharmaceuticals

It is proposed that the pharmaceuticals sector should form one of the main strands of the Team's work in 2005. The main reasons for proposing this include the following: (i) it is a major contributor to GDP; (ii) the sector is heavily regulated and there is a risk that activities such as R&D will move elsewhere if the regulatory regime is disproportionate; and (iii) organisations in the sector are keen for the Team to become involved.

Section 7: Other work

It is proposed that the Team also undertakes certain other work in 2005, relating to the following areas.

Construction – follow-up work

It is envisaged that, in general, work on regulation in the construction sector will be taken forward by the new industry-government group on policy and regulation (CIPER). However, work on the Construction Act Review is currently being taken forward as a separate project which is scheduled to continue until at least the middle of 2005. There is a case for BRT continuing to participate on this project. There may be other construction topics where BRT participation is desirable. For example, it is understood that ODPM may seek RIU's help in looking at alternatives to the Building Regulations for delivering an increasing range of objectives relating to sustainable communities.

Marine industry – follow-up work

A number of issues arising from the previous UK marine industry programme will require continued work in 2005 if they are not to adversely impact the industry. These issues include the following in particular:

- The Sound Emission Testing regulations came into force on 1 January 2005, but are not yet clear in their workings
- Levels of working with styrene are due to be re-assessed, and need to balance safety with the effects on small boat-builders
- The review of the Inland Waterways Hire Boat Code is not yet resolved

- Finally, there remain conflicts between EU and UK regulations on fire protection (small ships).

BRT will continue to work on these issues with the intention of achieving simplification and clarity of operation of these various regulations without imposing further burdens on a successful maritime industry which has a high density of SMEs.

Food

As a result of discussions with food retailers and producers and relevant trade associations, and building on the BRT's initiatives in the retail and waste management sectors, the BRT has decided to focus additional attention on the food sector in 2005. The review identified a number of candidate areas but the Team's resources will call for a focused effort in three specific areas of activity:

- *Industry-Government group.* Arising from BRT's work in the retail sector, the suggestion has been put forward that an industry-government group should be established for the food sector, along the lines of the VIPER group in the automotive sector and the new industry-government groups in the chemicals, construction and retail sectors.
- *Traceability.* A 2002 European Commission regulation on food safety (No. 178/2002) provides for the "traceability" of food and any other substance used in the production, processing, and distribution of food. This EC regulation has not yet been transposed in the UK. The BRT is interested in ensuring

that the transposition of this regulation achieves an appropriate balance between ensuring the safety of the food supply and the administrative burdens on food producers and processors, particularly SMEs.

- *Disposal of animal by-product waste.* A national association has expressed concern to the BRT about the small-business impact of regulations governing the disposal of animal by-products. The BRT is interested in exploring the treatment of unsold food products in its 2005 programme. The BRT will seek to determine if regulations are unduly burdensome for SMEs and, if so, what regulatory remedies would be appropriate.

Wind farms

Following dialogue with the offshore wind energy industry, the BRT has been looking at the potential for increasing joined-up working in this area across relevant Government Departments and Agencies, and how it might be further streamlined. We have been conducting an extensive initial round of exploratory discussions with all the relevant public and private sector stakeholders in the sector. The response has been positive and we have agreed that as a first step, we carry out an "information stocktake" of the extensive work already under way within Government departments and agencies on improving cross-departmental working. The intention of the stocktake is to explore ways of improving the processes by which offshore wind farm development is controlled and the extent to which impacts of wind farms on other users of the sea and on the environment is understood. We intend to contact all stakeholders to commence the information gathering process by the end of the year. Following receipt of responses in the early part of 2005, we propose to put our suggestions for next steps to all stakeholders shortly thereafter, for discussion.

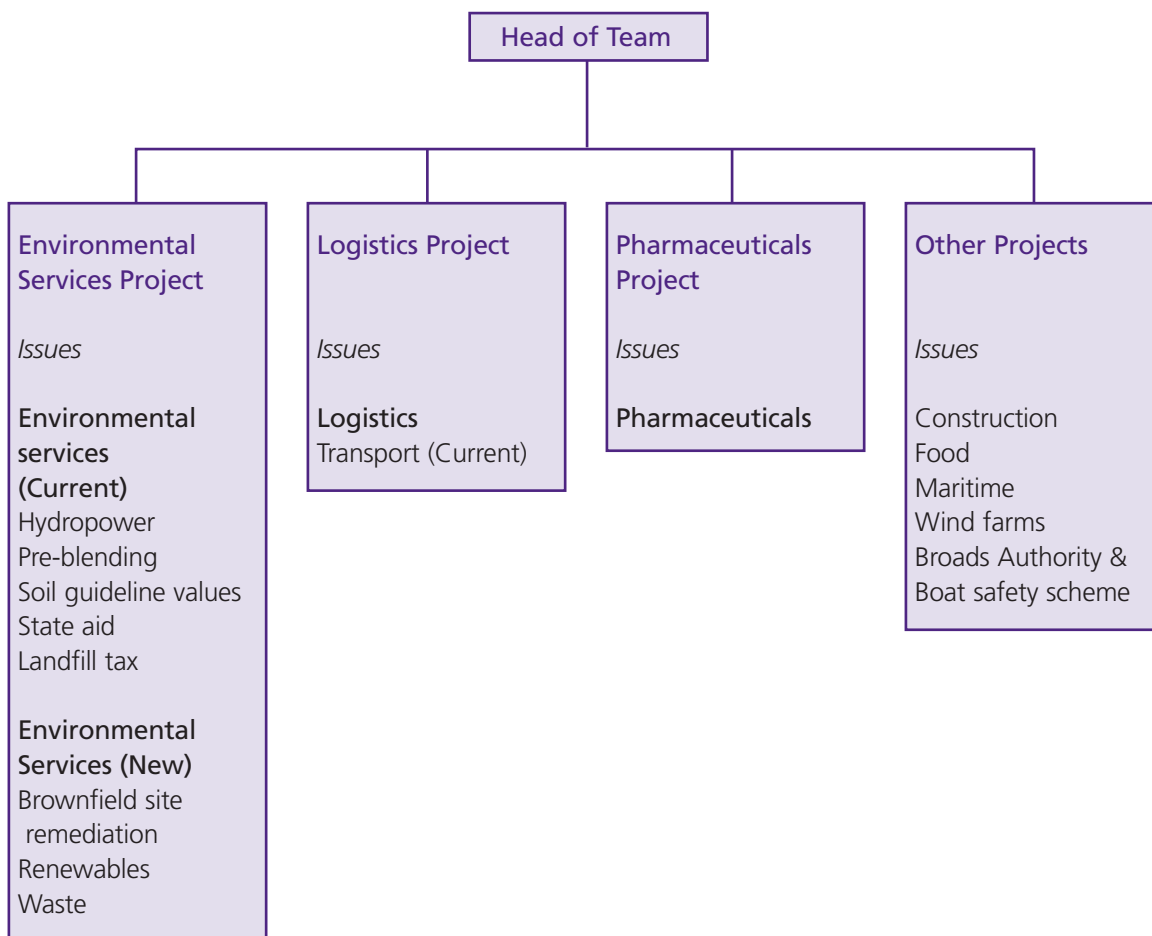
Conclusion – other work

It is proposed that the Team also undertakes certain other work in 2005 relating to the following areas: (i) follow-up work in the construction sector, such as ongoing work on the review of the adjudication and payment provisions of the Construction Act; (ii) follow-up work in the marine industry, such as on the sound emissions testing regulations; (iii) work on three main areas of food regulation: (a) establishment of an industry-government group on regulation; (b) traceability; (c) disposal of animal by-product waste; and (iv) work to improve the planning/consent processes for wind farms.

Section 8: Team organisation

An illustrative structure for the Team, to take account of the proposed 2005 work programme, is given below. The number of staff in the team is currently six, including the team leader.

Business Regulation Team – Illustrative Structure



Section 9: Conclusions

- **Environmental services sector.** It is proposed that work on the environmental services sector, which has been one of the three main strands of the Team's 2004 work programme, should continue to be one of the main strands of the Team's work in 2005. The main reasons for proposing this are as follows: (i) there is a large number of regulatory issues in the sector; (ii) many of the issues have links with key government policies (eg on renewable energy, recycling and the remediation of brownfield sites); and (iii) some of the team's current initiatives will take some time to come to fruition and should not be abandoned in mid-stream. Development on brownfield land is the subject of a national target – that 60% of additional housing should be on previously developed land.
- **Logistics sector.** It is proposed that the logistics sector should form one of the main strands of the Team's work in 2005. Reasons for proposing this include the following: (i) there is a significant demand from business to look at issues in this area following the whole supply chain rather than a single step in the process; (ii) the logistics sector is a major contributor to GDP; and (iii) it builds on, and significantly expands, the work on the transport sector carried out by the Team in 2004.
- **Pharmaceuticals sector.** It is proposed that the pharmaceuticals sector should form one of the main strands of the Team's work in 2005. The main reasons for proposing this include the following: (i) it is a major contributor to GDP with strong growth prospects; (ii) the sector is extensively regulated and there is a risk that activities such as R&D will move elsewhere if the regulatory regime is disproportionate; and (iii) organisations in the sector are keen for the Team to become involved.
- **Other work.** It is proposed that the Team also undertakes certain other work in 2005 relating to the following areas: (i) follow-up work in the **construction sector** (eg on the review of the adjudication and payment provisions of the Construction Act); (ii) follow-up work in the **marine industry**; (iii) work on three main areas of regulation of the **food sector**: (a) establishment of an industry-government group on regulation; (b) traceability; and (c) disposal of animal by-product waste; and (iv) work to improve the planning/consent processes for **wind farms**.

Annex A: Organisations and reports contributing to the Scoping Study

I ORGANISATIONS

GOVERNMENT, OTHER PUBLIC BODIES AND INDUSTRY/GOVERNMENT BODIES

Better Regulation Task Force
 Customs & Excise, HM
 Industry-government forums (chemicals, construction and retail sectors)
 Panel on Regulatory Accountability
 Treasury, HM

BUSINESS & INDUSTRY – GENERAL

Confederation of British Industry
 CBI – Trade Association Forum
 Federation of Small Businesses
 Forum for Private Business
 Institute of Directors

ENVIRONMENTAL SERVICES

The work undertaken during 2004 has involved contact with a large number of organisations with an interest in the sector. A list of these organisations is shown in the BRT's End of Year Report for 2004.

FOOD

National Association of Master Bakers
 Biscuit, Cake, Chocolate and Confectionery Alliance
 Federation of Food & Drink

LOGISTICS

British International Freight Association
 Freight Transport Association
 Road Haulage Association

PHARMACEUTICALS

Association of British Pharmaceutical Industries
 British Generic Manufacturers Association
 GlaxoSmithKline
 National Pharmaceutical Association
 Propriety Association of Great Britain
 National Office of Animal Health
 St George's Hospital Medical School

II REPORTS

'In their own words: red tape case studies from IoD members'. IoD. 19 July 2004. 71 pages.

'Lifting the Barriers to Growth in UK Small Businesses'. Federation of Small Businesses, 2004. See in particular Chapter 9 – Legislation, Regulations and the Environment.

'Mid-corporate growth survey'. Grant Thornton and CBI. November 2004.

'UK Environmental Regulation'. CBI. July 2004. 23 pages.

'UK Financial Services Regulation'. CBI. July 2004.

Reports (internal)

'Business Regulation Team: End of Year Report 2002'.

'Business Regulation Team: End of Year Report 2003'.

'Business Regulation Team: End of Year Report 2004'.

These reports are available on the Internet at: <http://www.cabinet-office.gov.uk/regulation>.

Annex B: Sector Weightings: Percentages of GDP (2002)

Group	Sector	£ million	% of GDP
A, B	Agriculture, hunting, forestry & fishing	9,035	0.98%
	Production		
C	Mining & quarrying	25,531	2.76%
D	Manufacturing	154,051	16.64%
E	Electricity, gas & water supply	15,181	1.64%
F	Construction	57,555	6.22%
G-Q	Service industries		
G	Wholesale & retail trade (including motor trade) repair of motor vehicles & household goods)	116,293	12.56%
H	Hotels & restaurants	31,554	3.41%
I	Transport storage & communication	75,661	8.17%
J	Financial intermediation	48,868	5.28%
	Adjustments for financial services	-44,211	-4.78%
K	Real estate, renting	218,663	23.62%
L	Public administration & defence	48,554	5.25%
M	Education	56,035	6.05%
N	Health & social work	64,515	6.97%
O,P,Q	Other social & personal services	48,304	5.22%
	All Industries	925,589	100.00%

Source: UK National Accounts: The Blue Book

Annex C: Sector Weightings: Percentages of FTSE All-Share Index (As at 31 August 2004)

FTSE All-Share sector weightings

Sector	Stocks	Index no	Adj mkt cap (GBPm)	Weight % All-Share
Mining	10	7032.31	53471	4.12
Oil & gas	16	5652.52	165271	12.74
Chemicals	11	1966.51	10882	0.84
Construction & building materials	41	2802.97	33500	2.58
Forestry & paper	1	8005.34	562	0.04
Steel & other metals	1	1059.18	1951	0.15
Aerospace & defence	9	1724.34	17427	1.34
Diversified industrials	0	1710.55	–	–
Electronic & electrical equipment	12	1554.83	3209	0.25
Engineering & machinery	23	2033.73	9995	0.77
Automobiles & parts	8	3689.23	3870	0.30
Household goods & textiles	6	4084.80	1201	0.09
Beverages	5	4013.30	36375	2.80
Food producers & processors	14	3169.92	29733	2.29
Health	12	3274.15	5959	0.46
Personal care & household products	4	4193.93	11496	0.89
Pharmaceuticals & biotechnology	17	7495.54	117051	9.02
Tobacco	3	11640.51	26081	2.01
General retailers	43	2102.29	48533	3.74
Leisure & hotels	31	3618.70	31081	2.40
Media & entertainment	38	3441.90	51854	4.00
Support services	62	3042.59	35812	2.76
Transport	28	2166.79	23394	1.80
Food & drug retailers	7	3114.04	30024	2.31
Telecommunications services	11	2505.56	111788	8.62
Electricity	4	3629.97	16579	1.28
Utilities – other	10	3906.59	36608	2.82
Banks	11	8606.27	254846	19.64
Insurance	19	853.73	6695	0.52
Life assurance	8	3875.35	34947	2.69
Investment companies	121	3423.79	31324	2.41
Real estate	31	2856.76	23880	1.84
Speciality & other finance	28	3424.14	19433	1.50
Information technology hardware	14	352.33	4000	0.31
Software & computer services	28	418.50	8518	0.66
FTSE All-Share	687	2214.19	1297352	100.00

Source: HSBC Research Report: 'All-Share Constituents & Weightings as at 31 August 2004' of 3 September 2004



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