EUROPEAN RISK FORUM – COMMUNICATION 01

UK BETTER REGULATION COMMISSION – CONTRIBUTION TO THE BETTER REGULATION STUDY ON EU AGENCIES

June 2007

1. EUROPEAN RISK FORUM

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of risk management issues at EU-level.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, costs, benefits, and legitimacy of different policy options (risk management).

- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;

- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice);

- The way in which risk management decisions are made should be structured, consistent, non-discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

Achieving these goals is, the Forum believes, likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and, extensive consultation.

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is produced and is made widely available to opinion-formers and policy-makers at EU-level. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. Indeed, direct engagement with opinion-formers and policy-makers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

The ERF is supported principally by the private sector. The ERF does not seek to promote any specific set of values, ideologies, or interests. Instead it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERF's work.

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2. BRC CONSULTATION

These comments have been prepared for the UK BRC (Better Regulation Commission) study of EU Agencies. They focus on agencies that form part of the EU's institutional architecture for assessing and managing lifestyle and technological risks to human health, public safety, and the environment. Comments cover four areas:

- Role of EU-level agencies in risk management (section 3);
- EU-level agencies and existing "Better Regulation" requirements (section 4);
- EU-level agencies and gaps in Better Regulation requirements – scientific advice and ex post evaluation (section 5);
- EMEA and the development of guidelines for new and existing veterinary medicinal products (section 6)

3. ROLE OF EU-LEVEL AGENCIES IN RISK MANAGEMENT

EU-level agencies perform three distinct roles within the European Union's institutional architecture for managing risks. Two of these are well understood whilst the third is not.

Formally, the EU's risk assessment agencies (such as EFSA and EMEA, and the new Chemicals Agency) are responsible for carrying out two functions; providing scientific advice to policy-makers and regulators; and undertaking case-by-case risk assessments as part of the process of implementing secondary, EU-level legislation.

Case-by-case risk assessments include reviews of the safety, quality, and efficacy of new or improved human and animal drugs, for example. These activities form part of the EU's functional separation of risk assessment and risk management, with the latter function being carried out by the Commission using the comitology process, in most cases.

The role of EMEA is, for example, to provide scientific opinions to the European Commission. Product licensing decisions, informed by these opinions, are then taken using the EU's regulatory standing committees – the risk management 'step'.

However, the scope of work of EU-level agencies is not confined to risk assessment. They also play a role in risk management. This occurs in a number of ways:

- **Guidelines** - Risk assessment agencies draw up and enforce the application of guidelines by companies seeking mandatory pre-market approval. These determine, for example, the test standards and methods that new or improved pharmaceutical products must meet if they are to meet safety, quality, and efficacy requirements set out in secondary legislation.

Guidelines provide officials with a flexible and speedy mechanism to respond to technical and scientific progress, as well as providing companies with a degree of certainty within the process of implementation of secondary legislation.

Such standards are, however, a form of 'soft law'. For most companies affected by guidelines, they define the legal requirement in detail. Failure to adhere to guidelines is, all too often, seen to be prima facie evidence of non-compliance. Moreover, guidelines often embed assumptions about the social acceptance of risk. For example, many guidelines include judgements that limit or prevent exposures through decisions about safety limits or test methods. This is a form of risk management.

Because of their impact on the time and cost of testing programmes needed to demonstrate compliance with legal requirements, guidelines developed by EU-level agencies can have an important negative economic impact on the development of new or improved products by companies.

A study carried out for IFAH, the trade association for the global animal health industry, provides evidence of the negative impact of EU-level guidelines on the time and cost needed to develop new products. In turn, this has contributed to fewer new products being introduced and greater use of older or existing product technologies in the EU. The study also provides a comparison with the situation in the USA. It concludes that the negative impacts of the regulatory system are greater in the EU than in the USA but finds no evidence that these greater costs are matched by increased social or environmental protection[1].

- **Labels and usage conditions** – EU-level agencies determine the details of user information and usage conditions that form part of the overall pre-market approval and marketing authorisation process for products such as human and veterinary medicines. These are risk management activities.

  User information seeks to inform user behaviour and is a well-understood way of managing risks. And, usage conditions are, in many cases, designed to reduce or eliminate specific exposures under conditions of use in the field. Again, this is a form of risk management being undertaken by EU-level agencies.

Recommendation:

Policy-makers should recognise explicitly that EU-level agencies play a direct role in the management of risks. "Better Regulation" policies and guidelines should take this into account.

[1] Business Decisions Limited 'Benchmarking the Competitiveness of the European Animal Health Industry' (2007)

[2] Whilst, pharmaceutical products are subject to ex post evaluations of safety and efficacy through the process of

4. EU-LEVEL AGENCIES AND EXISTING "BETTER REGULATION" REQUIREMENTS

Over the last decade, the EU has progressively introduced policies designed to improve governance and the quality of legislative decision-making. Activity has focused principally on two areas: consultation and impact assessment.

Initiatives have, however, focused on the development of new secondary legislation. In general, implementation of legislation, through technical regulatory decision-making processes, is excluded from the scope of the EU's requirements for impact assessment and consultation.

EU-level agencies are involved in all phases of the regulatory cycle at EU-level. Scientific advice, often provided by agencies, informs the development of new secondary legislation; agencies undertake case-by-case risk assessments and draw up guidelines as part of the implementation of legislation; and advice from agencies helps, in some instances, frame ex post reviews of secondary legislation.

As a general rule, however, the activities of agencies fall outside the EU's impact assessment and consultation requirements. This occurs for two reasons: first, the formal scope of the EU's requirements focuses on legislative rather than regulatory decision-making; and second, the EU's requirements have gaps – they do not yet cover key areas of work undertaken by agencies, most notably the provision of scientific advice.

In some cases, agencies have taken steps to remedy these problems. EMEA has, for example, established its own policies for the drawing up of new guidelines. These establish a formal and transparent process requiring officials to consult with stakeholders and to make assessments of costs and benefits.

But initiatives, processes, and standards differ between agencies. Moreover, whilst some secondary laws require consultation of stakeholders by specific EU-level agencies, there is no formal, EU-level requirement for agencies to carry out impact assessments.

Recommendation:

The scope and coverage of the EU's impact assessment and consultation requirements should be expanded to cover all of the risk management activities carried out by EU-level agencies, most notably the development or amendment of guidelines. As a part of this reform, officials in agencies should receive adequate training to enable them to undertake effective consultations and impact assessments.

5. EU-LEVEL AGENCIES AND GAPS IN BETTER REGULATION REQUIREMENTS

Taken together, the EU's Better Regulation requirements provide officials with a framework for making policy decisions. They define the coverage and operation of key parts of the decision-making process, for example.

This framework is, however, of a general nature. It is not tailored to reflect the needs of particular types of policy, legislative, or regulatory decisions. Because of the extent of the scope and complexity of policy areas for which the European Union is responsible, there are, unsurprisingly, gaps in the general Better Regulation framework.

For decisions that focus on managing the risks to human health, public safety, and the environment posed by technologies or by lifestyle choices, there are two important gaps in the coverage of the EU's policy-making framework. Specifically, policies and guidelines for the use of science in decision-making and for undertaking ex post evaluations are inadequate and incomplete[2]. These gaps, moreover, limit the impact of Better Regulation policies on the activities of EU-level agencies.

- **Scientific Advice** - One of the principal roles of EU-level agencies in the regulatory cycle is the provision of scientific advice to decision-makers. A recent report by the EPC, highlighted the lack of EU-level policies and guidelines to structure the effective and appropriate use of scientific evidence in decision-making. Major gaps identified by the report included a failure to define adequate quality standards for scientific evidence and to set out accepted methods for the interpretation of scientific evidence[3].

  Many of the concerns identified in the EPC's paper were confirmed in a recent evaluation of DG SANCO's non-food scientific committees carried out by RAND[4].

- **Ex Post Evaluation** - Good practices for making high quality risk management decisions (such as the framework developed in the USA during the late 1990s) suggest that ex post evaluations should form an integral part of the regulatory decision-making cycle.

  Although, there is some evidence of greater awareness and use of ex post analyses by the European Commission, there is, as yet, no substantive and complete policy framework and set of operational guidelines. Ex post evaluation is of particular importance for EU-level agencies because of the number of guidelines that are developed.

[2] Whilst, pharmaceutical products are subject to ex post evaluations of safety and efficacy through the process of pharmaco-vigilance, the guidelines used to determine standards of safety et al are not subject to ex post reviews.
[3] Bruce Ballantine 'Enhancing the role of science in the decision-making of the European Union' (EPC WP 17, 2005)
[4] RAND EUROPE 'Intermediate evaluation of the Directorate-General Health and Consumer Protection non-food scientific committees' (2006)

Recommendation:

The EU's Better Regulation framework needs to be expanded, if it is to improve the effectiveness and quality of activities by EU-level agencies. New policies and guidelines should be developed covering two areas; ex post evaluation and the use of science in decision-making.

6. EMEA AND THE DEVELOPMENT OF GUIDELINES FOR NEW AND EXISTING VETERINARY MEDICINAL PRODUCTS

Evidence from BDL's recent assessment of the impact of the EU's regulatory framework on the competitiveness of the animal health industry suggests that some progress has been made by EMEA in embedding Better Regulation policies into the process for developing new guidelines for safety, quality, and efficacy testing. EMEA's guidance note in this area is an example of a "good practice" and should be highlighted.

Whilst recognising the progress made by EMEA, animal health companies raised a number of concerns about the new process specifically and about risk management decision-making by EMEA in general:

- More effort is needed, companies argue, to ensure that the need for a new guideline is based on a relevant and realistic assessment of risk (rather than hazard or theoretical exposures). Moreover, the need for action should be subject to more intensive and earlier public scrutiny by stakeholders than is currently the case.

- Decisions need to be more fully informed by analyses of the costs and benefits of different ways of meeting policy objectives, companies suggest. At present, the level of technical awareness of costs and benefits is, in many cases, embryonic. This limits the scope for effective comparisons between policy options.

- Assessments of costs and benefits of different options should take more account of the possibility of creating negative unintended consequences – the so-called "risk-risk" paradigm.

- In too many cases, officials and scientists fail to recognise that they are making risk management decisions, companies argue. For instance, new test guidelines are, in most cases, automatically applied to old animal health products; a process known as "retrospective application". In the past, this has triggered new mandatory spending on old products ("Defensive R&D), leading to major reductions in product availability and lower levels of innovation. A decision to retrospectively apply new requirements to existing products is a form of risk management and should be assessed as one of a number of possible policy options rather than being selected automatically. Unless this retrospective application is justified by evidence of risk, it creates major socio-economic

problems due to loss of availability of medicines for animals. (The scale of this problem is explained in BDL's recent report.)

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Recommendation:

The use of consultation and impact assessment by EMEA should be highlighted as a good practice. However, the limitations of the model established by EMEA should be recognised and improvements implemented.

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