lated medicinal[8] and pharmaceutical[9] product information. These instruments provide guidance in the definition of the concepts of substances[10] and specified substances taking into account challenging new areas such as advanced therapies. Furthermore, the standards provide terminology specifications (including translations and versioning) as well as recommendations on the mapping of terms already used by stakeholders to the described concepts, with main emphasis on pharmaceutical dose forms, units of presentation, routes of administration, packaging[11] and units of measurement[12].

The five IDMP standards are designed to support the primary objectives of the regulation of medicines and the activities of medicines regulatory authorities worldwide. These include a variety of aspects related to development, registration and life cycle management of medicinal products as well as risk management and pharmacovigilance, the latter specifically by fully integrating IDMP with the ICSR standard.

Unique identifiers produced in conformity with the IDMP standards are intended to support applications where it is necessary to reliably identify and trace the use of medicinal products during their entire life cycle. As for the ICSR, the IDMP standard will make use of HL7 messaging tools capable of supporting the entire life cycle management of medicinal products and is expected to be finalised by the end of 2011.

ICH is now in the process of defining the way the ICSR and IDMP standards should be implemented and used. The development of 'ICH Implementation Guides' has been initiated as a new approach to communicating requirements and addressing regulatory, scientific and technical harmonisation challenges at international level.

The next few years will prove to be both challenging and exciting for medicines regulatory authorities, pharmaceutical industry and the healthcare community in responding to the needs of a society that is increasingly dependent on electronic communications and information technologies. It is worth mentioning the efforts of SDOs to make contributions in the emerging domain of "health informatics", and that the outputs of this exercise will be taken into account by the ICH. Global standards are becoming increasingly important from a strategic perspective, not only for improving competitiveness of enterprises[13] but more importantly for the way in which they will facilitate regulatory activities, improve the monitoring of the safety of medicines and strengthen the protection of public health.

8 Draft International Standard prEN ISO 11615 Health Informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated medicinal product information.

9 *Ibid.*

10 Draft International Standard prEN ISO 11238 Health Informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated information on substances.

11 Draft International Standard prEN ISO 11239 Health Informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging.

12 Draft International Standard prEN ISO 11240 Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of units of measurement.

13 Communication from the Commission to the European Parliament and the Council on the Role of European Standardisation in the Framework of European Policies and Legislation COM (2004) 674 fin.

Regulatory Impact Assessment

This section regularly examines Regulatory Impact Assessment (IA) at three levels: the EU, the Member States and internationally. Contributions aim to cover aspects such as the interface between IA and risk analysis, looking at methodologies as well as legal and political science-related issues. Contributions are meant to report and critically assess recent developments in the field, develop strategic thinking, and make constructive recommendations for improving performance in IA processes.

Regulatory Impact Assessment and Sustainable Development: Towards a Common Framework?*

*Klaus Jacob***

I. Introduction

In May 2009, the German Federal Government introduced the requirement to perform a sustainability assessment on new legislation as part of its general Regulatory Impact Assessment (RIA). New legislation must now be assessed on its likely impacts on the 21 priority areas of the German national strategy for sustainable development. So far, there is no experience of the methods and processes for such

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assessments, thus leaving room for learning from other cases and examples of how Sustainability Impact Assessments are undertaken in other countries. A study commissioned by the German Bertelsmann Foundation has analysed this topic.[2]

In theory, the ex-ante Impact Assessment of policies is a powerful tool for integrating concerns of Sustainable Development (SD) as well as other cross-cutting strategies into sectoral policy-making. Still, there are only a few countries that explicitly refer to issues of sustainability in their guidelines for Impact Assessment (IA), most notably the United Kingdom, Ireland, Switzerland and Belgium. In addition, the European Commission perceives its impact assessment procedures as a tool to ensure the sustainability of European policies. Although all countries pursue the common goal to ensure coherence of new legislation with issues of sustainable development, the systems and practices of Sustainability Impact Assessment (SIA) differ considerably. In the following , some of the main features and related issues will be discussed and conclusions will be drawn for possible future directions in IA.

All jurisdictions mentioned above have several years of experience following their decision to develop a SIA. The UK pioneered the integration of SD criteria in their RIA in the 1990s. The European Commission followed in 2003, Switzerland in 2004, Ireland in 2005 and Belgium in 2007. In all countries the introduction was made by government decision, with the exception of the UK, where it was established on the basis of a law.

II. Sustainability Impact Assessment (SIA) and the general RIA procedures

The relation of SIA to and its degree of integration in, the general IA systems vary. In the European Commission and in Ireland, SD criteria are fully integrated into the general system of IA. In contrast, SIA has been designed as a separate module in Switzerland and in Belgium. In these countries, every new piece of legislation has to undergo different tests along with the SIA. In Germany, SIA is part of the general IA system, but it is highlighted in the annex of the (non-binding) guidelines. Up to now, there has been too little practice to assess whether the assessment will be integrated into the general system or whether it will rather be applied as a separate module.

The UK is an exception. Since the 1990s, additional assessment criteria including SD issues, have been merged into a single integrated system of RIA. In the latest reform in 2007, the RIA system was split into several modules which are to be applied if there is evidence for a planned policy being relevant to issues of the respective module. In any case only the calculation of financial costs and benefits has to be made, while other aspects, including social and health aspects, are only being applied on request of the department responsible for the respective issue area. Sustainability is one of these modules, but there is neither a dedicated institutional responsibility for this module nor has it been applied so far.

Given the multidimensional concept of sustainable development, it appears to be more appropriate to integrate its assessment into a single system in order to avoid duplication of criteria. The separated approach also has advantages: a focused approach with clear goals is more open to quality control, is less ambiguous than a holistic approach, and is more open to political support as it may better reflect the political priorities of the government. The example of administrative burden testing, which is successful in many different jurisdictions, can be seen as a role model: the focused, single issue approach received political support from their respective heads of governments in many countries. It remains to be seen however, whether this success can be applied to the SIA as well – evidence from Switzerland, the reformed system in the UK and Belgium is not promising. When applied at all, the SIA did not develop beyond pilot testing.

III. Internal and external consultation

Another aspect in which the countries vary is the level of participation and consultation both internal, within governments and external, with stakeholders. In Belgium, SIA is organized as an internal process: Only the responsible department is in charge of the SIA, and there are no requirements for the involvement of other departments or external stakeholders. In Germany, IA is undertaken by the lead depart-

2 See Klaus Jacob, Julia Hertin and Sylvia Veit, "Gestaltung einer Nachhaltigkeitsprüfung im Rahmen der Gesetzesfolgenabschätzung", Studie der Freien Universität Berlin im Auftrag der Bertelsmann Stiftung, available on the Internet at <http://www.polsoz.fu-berlin.de/polwiss/forschung/systeme/ffu/publikationen/2009/jacob_klaus_veit_sylvia_hertin_julia_2009/09_nhp_gutachten.pdf> (last accessed on 19 July 2010).

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ment, but other departments are able to ask for additional analysis if they fear impacts on their domain. However, this almost never happens. The UK and the European Commission (EC), in contrast require extensive consultation among departments involved. In the EC, interdepartmental working groups are set up to prepare and accompany IA exercises. The UK, the EC and also Germany require public consultation as part of the IA. In the UK and the EC this is a highly formalised procedure. For Ireland and Switzerland, there is no data available on the level of internal and/or external participation.

An exclusively internal SIA has the advantage that resource use is small, and political interference and conflicts are avoided in the early stages of decision-making. On the other hand, IA with intensive participation and consultation has the advantage that other sources of knowledge can be utilised. Furthermore, the requirements for consultation provide incentives for the responsible unit to enhance quality of the IA analysis. Additionally, if stakeholders are involved in the setup of IA studies (e.g. scope, research questions, methods, etc.), acceptance of their results is likely to be higher and hence conflict over the appropriateness of IA can be avoided.

However, with increased participation and consultation, transaction costs cannot be avoided, and this gives the participants opportunities to exert influence on decision-making earlier in the process. This in turn is an incentive for the responsible units not to collaborate intensively and not to disclose information about the analysis. The example of Germany, with its constitutionally guaranteed independence of the departments, shows that the level of cooperation depends largely on the institutional context in which IA is conducted. While there are examples of inter-departmental IA in Germany these are exceptions rather than the rule. Generally speaking, it is quite possible for individual departments to get out of collaborative preparation of legislation if political conflicts arise.

IV. Timing of Sustainability Impact Assessment

All countries describe IA in their guidelines as a process rather than a one-off activity. The practice of IA, however, is different. IA is most often conducted at a discrete point of time and often only done shortly before the submission of the proposal to the cabinet. This requires the least resources, but it is rather unlikely that the results of the analysis will have any impact on the decision. The analysis usually comes in too late, as there is already political commitment. In the UK and the EC, and several milestones of the legislative process have been defined which have implications for the IA process as well. Examples are the EC roadmaps for planning IAs, consultations and publications or reviews by agencies on the quality. By this means, it is more likely that the IA is organised as a process instead of a single event.

V. Criteria for the assessment

Countries can be categorised according to the type of criteria used for impact assessment. We can distinguish three models: (1) no obligatory impact areas, (2) defined criteria for the purposes of the SIA, and (3) reference to the priority areas of the national strategies for sustainable development. The European Commission and the UK have no fixed set of impact areas. Instead, the guidelines provide a set of questions or suggestions, but the specific impact areas are determined according to individual policies. Belgium and Switzerland have developed specific criteria for the purposes of SIA. In Belgium, a questionnaire with 33 items exists and in Switzerland 15 questions have to be answered for the identification of relevant criteria, and 27 aspects have to be considered during the assessment. In Germany and Ireland the criteria are directly derived from the national strategies for sustainable development. In Ireland seven impact areas are mentioned and in Germany the 21 indicators of the strategy together with 10 management rules constitute the SIA impact areas.

The model of an open approach for determining the impact areas appears to be most appropriate for the many different policies at stake and for the wide range of impacts which are hard to predict. This openness is, however, inevitably linked to a high level of ambiguity with regard to the requirements for a specific IA. This can be avoided by using a fixed set of criteria or questions. However, there is the risk of closing down the assessment too early and thus important aspects might not be considered because they are not reflected in the questions or criteria. Deriving impact areas from the strategies for sustainable development provides a higher degree of legitimacy and political relevance for the criteria. Furthermore, the determination of fixed criteria for all policies and policy domains has the advantage of easier quality control.

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VI. Methods for Sustainability Impact Assessment

Regarding the methods used for SIA, the UK guidelines recommend translating all impacts into monetary costs and benefits in order to allow aggregation and estimation of the net benefits (or costs) of a planned policy. The EU and Ireland guidelines recommend using cost benefit analysis as often as possible, but also taking certain aspects into consideration that cannot be expressed in monetary terms. In such cases, the assessment methods, the aggregation of impacts and the comparison of options for these specific cases have to be decided upon. In Germany, no methods are specified at all. In Belgium and Switzerland, checklists are available which allow at least a scoping of relevant aspects.

The multidimensional concept of sustainable development includes many aspects which are quantifiable with difficulty within reasonable effort, or they cannot be captured by a single method then aggregated and compared to each other. In particular, the assessment of trade-offs between different dimensions of sustainable development are inevitably linked to normative decisions and hardly belong to a purely analytical task only. However, the standardisation of methods also has its advantages: reducing ambiguity and allowing quality control. The standard cost model for the analysis of administrative burden serves as role model – it is easily applicable and its appropriate use can be monitored.

VII. Quality control

Finally, the mechanisms for quality control differ considerably between countries. The following mechanisms can be identified. In some jurisdictions, several mechanisms are applied:

- internal control as part of the interdepartmental coordination, in some cases with a coordinating department (UK: Better Regulation Executive; European Commission: Secretariat-General and Ireland: Better Regulation Unit) or without a dedicated institution (as in Germany);
- dedicated body with the authority to ask for additional analysis (European Commission: Impact Assessment Board; Germany: Parliamentary Council);
- transparency which allows IA to be scrutinised by the general public, by academics or by interest groups (UK, European Commission, partly Ireland);
- evaluation of the system performance, i.e. IAs are not evaluated singly but as part of the overall performance of the IA system (UK: evaluations by the National Accounting Office; European Commission: evaluations are carried out by commissioned evaluation studies).

No mechanisms for quality control have been identified in Switzerland or in Belgium.

The role model of an independent body of experts installed for overseeing the administrative burden testing in several European countries (like Actal in the Netherlands or the *Normenkontrollrat* in Germany) has nowhere been set up for SIAs. Neither has the mandate of existing bodies been extended to other domains of IAs, notwithstanding the testing of administrative burden. The recent German approach to mandate a parliamentary committee is innovatory. The committee has started the review of SIA only recently and gives recommendations to the parliamentary committee, which is responsible for the policy domain covered by the respective proposal. The committee is then free to decide whether to return the proposal to the government with the request for additional analysis or to dismiss the recommendations. It remains to be seen whether the quality control by the parliament will provide sufficient incentives for officers to conduct a sufficient in depth analysis of their proposals.

VIII. Can RIA and SIA be bridged?

The comparison of the different systems for the assessment of impacts on SD reveals that there is no uniform approach in all countries. Instead, there is considerable variation among the different dimensions of IA. But what are the requirements for a SIA? How far is SIA possibly different from RIA and would it need a different treatment? What can be reasonably expected from SIA?

Clearly, the concept of SD implies an analysis of environmental, economic and social impacts to demonstrate possible trade-offs between these dimensions. This implies that not only the intended impacts of the legislation need to be analysed. Possible side effects require additional attention, too. The scope of the analysis will have to be determined using either a fixed set of criteria reflecting the political priorities or criteria which have been negotiated in internal or even external consultations. SIA is therefore not only an analyti-

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cal tool that may predict the outcomes and impacts of a planned policy, but it is also a communication tool on relevant aspects, expectations and finally also on judgments. For the criteria of cost-effectiveness or efficiency, it is easy to rank different options on the basis of a single dimension. In case of trade-offs between the different dimensions of SD, this is hardly possible. How should potential trade-offs between employment, economic prosperity and natural capital be judged? This task is obviously not only analytical, but also encompasses normative decisions. Certainly this cannot be left up to the sole responsibility of the unit which is responsible for the preparation of the legislation and the IA. Compared to standard RIA, a SIA is potentially subject to wider politicisation.

Another important aspect of SIA is the need to assess the long-term impacts of policies: How far are the burden, costs and the return of investment of a planned policy distributed over time? Typically, future generations have very little say in the political process. In the negotiations on political decisions and in finding compromises, future generations are weakly represented. In the context of SD, it is an important objective to analyse whether costs are going to be imposed on future generations rather than only analysing the distributional impacts among different societal groups. If a return of investment can be demonstrated in the long term, it may contribute to increasing the legitimacy of political decisions.

Impact assessment, and in particular SIA, has to find a role within the institutional context of decision-making. The frequent call for more evidence in decision-making is particularly necessary in the face of the requirements of SD. However, this has to fit into the rationality of the political process. On the one hand, SIA requires resources and opportunities for analysis, and on the other it requires a demand from decision-makers who utilise the results.

Risk Communication

This section discusses issues related to risk communication across a range of publicly perceived high-risk industries (such as pharmaceuticals, nuclear, oil, etc.). It reports critically and provides analysis on risk communication as an outcome of risk research within these industries. Contributions are intended to include methods working towards the advancement of risk perception research and describe any lessons learned for successfully communicating to the public about risk.

Can Practitioners Do Better at Risk Communication? Using Evidence to Develop Best Practice

*Frederic Bouder**

The best way for practitioners to improve their skills in effective risk communication is to take on board the decades of research in this area. Risk communication has its roots in risk perception studies and has evolved as a rich and diversified research field. It has undergone an evolutionary process from top-down information towards two-way and proactive exchanges. Today, guidance is available to support practitioners' efforts. "State of the art" risk communication is attainable. Finally, moving guidance documents from rhetoric to reality often implies procedural and managerial adaptation.

I. Introduction

Many practitioners struggle when trying to communicate scientific information. Indeed, it has been known for poor risk communication to add fuel to risk controversies, quite independently of the quality of the risk assessment or the level of uncertainty involved. Well-known examples abound, from BSE[1], to dioxin in chicken[2] or vaccine scares[3]. On the other hand, there is also evidence of successful risk communication. The Leiss volumes[4] and the

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1 Douglass Powell and William Leiss, *Mad Cows and Mothers Milk* (Montreal: McGill-Queen's University Press 1997).

2 Corie Lok and Douglass A. Powell, *The Belgian Dioxin Crisis of the Summer of 1999: A Case Study in Crisis Communication and Management* (Guelph, Ont.: Department of Food Science, University of Guelph 2000).

3 Richard Horton, *MMR: Science and Fiction* (London: Granta Books 2003); Frederic Bouder, "A Comparative Analysis of Risk Perception Related to Human Health Issues", in Ingo K. Richter, Sabine Berking and Ralf Müller-Schmid (eds), *Risk Society and the Culture of Precaution* (Basingstoke: Palgrave Macmillan 2006).

4 William Leiss and Christina Chociolko, *Risk and Responsibility* (Montreal: McGill-Queen's University Press 1994); William Leiss, *In the Chamber of Risks: Understanding risk controversies* (Montreal: McGill-Queen's University Press 2001); Powell and Leiss, *supra* note 1.

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