

Health Governance in Europe

Issues, challenges and theories

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Bridging European and member state implementation

The case of medical goods, in vitro diagnostics and equipment

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Introduction and background

Everywhere, enormous changes in the health sector are under way. Some are driven by globalizing forces and regional integration, while others result from domestic healthcare reform. European regulatory integration and healthcare reform have combined to move medical supplies and patient-supporting and life-sustaining aids and heavy equipment closer to centre stage in policy-making and technology assessment. There is increasing concern for the quality of medical services, as well as for medical vigilance of accidents associated with the use of medical devices. There is a growing realization that medical, environmental and food risks to health need to be managed better than they have been in the past. Will the management of health risks - perceived or actual - become a vehicle for opening up currently closed channels of problem-solving, information, transparency and accountability at both the European and national levels?

This chapter grew out of an interest in European integration, as well as the discovery a few years ago of a dearth of information on the medical device sector, which is in striking contrast to the comprehensively researched pharmaceutical sector (Altenstetter 1994, 1998a, b). Yet medical devices are central to clinical practice and patient and home care. They are at the heart of diagnosis, treatment, prevention and rehabilitation, and are the engine that drives medical progress and innovation. The lack of attention paid to these devices was surprising, especially at a time when a debate about cost containment raged in every single member state of the European Union, and medical devices had begun to come under the scrutiny of public payers. In its resolution of 7 May 1985 the European Council had addressed the concerns of the medical device industry by developing the so-called *new-approach* legislation for product regulation, and by adopting the global approach to conformity assessment (Commission of the European Communities 1994, 1999), affecting seventeen industrial sectors including medical devices.

Medical devices actually are an ideal entry point for the exploration of

the effects of European regulatory integration: varied outcomes affecting national regulators, products, manufacturers and distributors, purchasers/payers, users, patients, and the global medical device market itself can be observed. Although most device-related issues are primarily framed in terms of trade, medical device issues really concern public health. As such, they raise complex cross-cutting issues, internal and external to the healthcare system, which intersect with other debates involving scientific knowledge in several disciplines, as well as political judgements.

The international health policy community and European integration specialists share with policy-makers, patients and users the assumption that the products used in clinical practice and home care are safe and of good quality, and perform as intended by their manufacturers. However, this is not always the case. Whether patients are recipients of prescription drugs, medical devices or transplanted tissues does not make a difference; nor is it a concern whether devices incorporate drugs, whether drugs need a medical device for delivery to the patient (for example, an asthma inhaler), whether medical devices are transplants, or whether products incorporate human cells, biologically or pharmacologically active substances, or synthetic device-like structures, as long as they can be used safely and effectively. However, these differentiations matter a great deal for the development of a legally clear and fair regulatory regime, appropriate regulatory strategies, and feasible mechanisms for compliance, enforcement and implementation. Regulation is treated as a distinct type of policy-making (Majone 1996,1997; Lowi 1964).

A 'right' theory of implementation?

To implement is to interpret and execute political decisions. Yet implementation involves more than simply translating intentions into decisions and action. In the European context it is also about collective and individual learning through trial and error over time (Commission of the European Communities 2003a) and adaptation of European regulatory requirements into national contexts. The debate about the 'right' theory of implementation and, in particular, between the proponents of 'bottom-up' versus 'top-down' perspectives has generated an abundance of literature. Similarly sterile academic debates about European integration continue between intergovernmentalism and neo-functionalism, and supranational governance (Sandholtz and Sweet 1998).

Theoretically, this research focuses instead on fairly standard questions raised in the tradition of domestic implementation research (Najam 1995; Goggin *et al.* 1990; Elmore 1979). In this research tradition, implementation means tracing the effects of policy on target groups and assessing final outcomes. This analytical focus is quite different from the unique, legalistic meaning it is given in the European Union-member state nexus (Mendrinou 1996), which has increasingly come under criticism recently (Borzel

and Cichowski 2003; Stone Sweet 2003). Drawing a distinction between pre-decision and post-decision processes of bargaining over compliance with EU rules, Tallberg and Jonsson (2001: 2) identified three bodies of literature: public policy research on implementation; legal and political research on the European Commission's execution of its functions as 'guardian of the treaties'; and legal and political research on the interaction between the European Court of Justice (ECJ) and national courts in the decentralized enforcement of EC law. Each research school uses compliance, enforcement and implementation slightly differently; and the analytical focus rarely extends past the relations between EU institutions and member states.

The core issue for domestic implementation research is: what happens to EU directives after they are transposed into national law? What adaptations to national and local practices are made? Are additional national requirements added to EU regulations? Blueprints such as the transposed legislative texts specific to medical devices hardly provide answers to these questions. Nor does the literature on EU compliance, enforcement and implementation serve as a basis for plausible statements about potential outcomes, since this literature primarily addresses the nexus between the European Union and the member states. In order to find out more about adaptation and transformation processes, two steps should be taken. First, a more *problem-oriented* rather than legalistic perspective of implementation needs to be adopted; 'the facts' and 'reality' about implementation need to be discovered from those directly involved in the process. Second, the meaning that policy actors give to EU directives once they are transposed into national law needs to be revealed, along with the mixture of meanings and practices that emerge from shared policy arrangements over the regulation of medical devices and prior national practices (Yanow 1996). Moreover, as Scharpf noted nearly three decades ago:

[i]t is unlikely, if not impossible, that public policy of any significance could result from the choice process of any single unified actor. Policy formation and policy implementation are inevitably the results of interactions among a plurality of separate actors with separate interests, goals, and strategies.

(1978:347)

After thirty years of research on domestic implementation, a scholarly consensus on a broad research design has emerged, despite disagreements on some fine points. Five clusters of factors are hypothesized as shaping, though not determining, the process of implementation and final outcomes. For this research project, the 'critical' components are:

- the *content* of policy before and after EU directives and the Community regulatory regime;

- the *context* (the degree of dominance of organizational actors);
- *commitment* in support of or in opposition to EU regulatory policy;
- *capacities* (manpower, skills, funds, information and communication);
- *clients and coalitions* (target groups affected by EU regulatory policy, which include regulators, notified bodies, manufactures, clinicians, nurses, patients, home caregivers, tissue banks, reimbursement bodies, etc.).

A discussion of regulatory policy *content* and *context* requires further explanation. The challenges for identifying content and context are huge. Not only are national officials 'setting' and 'shaping' EU regulatory policy (Peterson and Bomberg 1999), they also are key players in domestic enforcement, monitoring of compliance, and implementation. This dual role justifies examining EU policy-making at length in a study that primarily focuses on domestic implementation. The traditional paradigm of law and public administration, as well as an assumed hierarchy of commands and controls, is widely used in European integration studies. However, from a problem-oriented domestic implementation perspective, this framework can be misleading. If we recognize that pure hierarchies hardly exist, the concept of 'policy networks' of interacting actors operating at different levels of decision-making and action is more appropriate (Heritier *et al.* 2001; Ladeur 1999; Altenstetter 1994, 2001). Yet one should not overstate the importance of informal compared to formal provisions either. In regulatory policy, a formal-legalistic paradigm constitutes reality in the everyday life of a good many policy actors and relates to important systemic conditions (legal-administrative, professional, political). Centrally legitimized norms and rules, and standard operating procedures (SOPs), are ubiquitous and influence adaptation processes at both European and national levels (Altenstetter 2003a, 2005). Domestic central actors expect these mandates to be enforced in a fairly streamlined implementation process. Yet such rigid control and command mechanisms have never existed in the fifteen pre-2004 EU member states, nor in any democracy. Nor do they exist following the enlargement in 2004. On the contrary, national variations in implementation have significantly increased. Within their respective constitutional structure and legal and administrative traditions, France, Germany and the United Kingdom have placed a premium not only on centralization but also on decentralization, and have felt the need to strike a balance between European and national central mandates and their larger home environments. They all experience strong pressures for decentralization, regionalization, and devolution of government tasks.

EU regulatory policy on medical products is embedded in the creation of the single market and the *new approach* to regional integration and technical harmonization, thus launching a new era in regulatory policy. Historically, the regulation of medical devices in the member states prior to 1985 was connected with market correction rather than market cre

ation. This novel element raises a number of salient issues about the goals and impact of EU regulatory policy on domestic implementation. In what follows, a brief overview of the regulation of medical devices in the European Union is presented. In order to situate EU decision-making on medical devices within the larger framework of EU governance, I draw on secondary literature by presenting the core characteristics of decisionmaking by EU institutions. I then examine medical device regulation by committees. Finally, I examine the highly unusual directive on diagnostic products and domestic implementation.

Regulating medical devices in the European Union and beyond

The general policy on the single market provides the basic framework for the three medical device-specific directives. The Council Directive on Active Implantable Medical Devices (AIMD, 90/385/EEC) of 20 June 1990 has been in force in the member states since 1 January 1993, and the Council Medical Device Directive (MDD, 93/42/EEC) since 1 January 1995. The MDD covers all products that are neither implants nor in vitro diagnostic products. After a delay of more than seven years, the In Vitro Diagnostic Directive (IVDD, 98/79/EC) for in vitro diagnostic devices was finally published on 7 December 1998 in the *Official Journal of the European Communities*. Not unexpectedly, the IVDD amended the two prior directives in important ways, as will be detailed below. The IVDD was supposed to come into force on 7 December 1999 but was postponed to 7 June of the following year because no member state had met the deadline. Variable transition periods for placing devices on the market applied until 2003, and for putting them into service until 2005. A series of amendments and additional directives have been put in place since then.' However, the focus in this contribution is on the three central directives, which roughly correspond to three very different industrial sectors, as documented in Table 3.1.

Medical devices are classified according to a fourfold scheme of risks understood in terms of duration of contact with the human body, degree of invasiveness, and parts of the anatomy affected. Risk levels are not identical with the three product categories shown in Table 3.1. Worldwide, there are about 100,000 low-risk devices (Class I) on the market, 10,000 medium-risk devices (Class IIa), 1,000 higher-risk devices (Class IIb) and about 100 of the highest-risk (Class III). The stricter the risk, the higher the regulatory requirements. Over the past ten years the most intense controversy has centred around Class IIb and Class III devices and medical devices that are at the borderline between medical devices and pharmaceuticals such as diagnostic products. Some argue that these should be treated like drugs and thus fall under drug regulation, while others insist that several items in these two classes should be subject to tougher

Table 3.1 The heterogeneity of medical devices

Anaesthetic and respiratory equipment: CEN/TC 215°		Implants for surgery: CEN/TC 285	
1	Tracheal and breathing tubes	9	Cardiac implants
2	Anaesthetic machines	10	Vascular implants
3	Medical breathing systems	11	Osteosynthesis implants
4	Medical gas supply systems	12	Reconstructive implants
5	Lung ventilators	13	Joint replacement tools
6	Pressure regulators	14	Mechanical contraceptives
7	Flow-metering devices		
8	Connectors		
Non-active medical devices: CEN/TC 205		Electrical equipment	
15	Urinary and drainage catheters	29	X-ray equipment
16	Hypodermic syringes and needles	30	Medical electron systems and accelerators
17	Plasma filters	31	Cardiac defibrillators and monitors
18	Condoms	32	Ultrasonic therapy equipment
19	Extra-corporeal circuits	33	Nerve and muscle stimulators
20	Blood gas exchangers	34	Lung ventilators
21	Transfusion and infusion sets	35	Electroconvulsive therapy equipment
22	Parenteral devices	36	Endoscopic equipment
23	Medical gloves	37	Baby incubators and radiant warmers
24	Clinical thermometers	38	Electrocardiography
25	Anti-embolism hosiery	39	Blood pressure monitoring equipment
26	Pen injectors	40	External cardiac pacemakers
27	Enteral feeding tubes	41	Magnetic resonance equipment
28	Surgical tapes and gowns	42	Heated pads, blankets and mattresses
		43	Electrically operated hospital beds

Source: Adcock, Sorrel and Watts (1998).

Note

a CEN is the European Standardization Committee (Comité Européen de Normalisation TC translates into Technical Committee.

requirements. Some Class IIb products such as breast implants were recently reclassified as Class III,' and a proposal to bring all borderline high-risk products under the pharmaceutical regime has had its first reading in the European Parliament.

In July 2003 the Commission accepted the June 2002 report by the Medical Device Expert Group (MDEG). According to this report, the legal framework concerning safety aspects and technological evolution is appropriate. However, the report noted that there was ample room for improving domestic implementation through the coordination of postmarket surveillance and vigilance, improving the European Union Data

base for Medical Devices (EUDAMED), more consistency in clinical investigations, better checks over conformity assessment, more transparency and mutual trust among the member states, improved market surveillance, and better cooperation between the Commission and member states (Commission of the European Communities 2003b). Finally, the MDEG proposed yet another High Level Committee for Medical Devices.'

A comparison of the different pathways to market authorization for medical devices and pharmaceuticals indicates the linkages between the two regulatory regimes, especially concerning the AIMD and the MDD. In prior research I found major differences in terms of the historical timing of regulation, principles of market authorization and strategies of European regulatory policy, including the strengthening of post-market surveillance and improvement of medical vigilance systems (Altenstetter 2002; Commission of the European Communities 2003a). A brief summary of the essential components of EU medical device regulation, as exemplified in the AIMD and MDD, follows. It shows how much leeway is left to the member states, despite regulatory harmonization at the EU level.'

Regulatory policy on medical devices is based on five principles implied in *new-approach* legislation. First, CE-markings serves as a guarantee of conformity with particular EU regulations or directives. The mark is a kind of market authorization, but should not be confused with the premarket approval or licensing of individual products or the strict product testing regime in the pharmaceutical sector, which is subject to *old-approach* legislation.' Second, EU directives, which need to be transposed in their entirety into national law, specify the essential requirements (technical-scientific and clinical) in highly detailed annexes. These requirements must be met as a precondition to market authorization. Third, these annexes reference harmonized European standards (EN) or international standards by the International Organization for Standardization (ISO), rather than national standards. Within this framework the member states have considerable discretion. As a fourth principle of the new approach, member states can invoke the safeguard clause - Article 36 of the Treaty of Rome - in the interest of public health. Such action should be based on reasonable doubt that essential requirements for products are in fact respected, or on evidence that product standards are applied inappropriately or do not exist. Member states can act within parameters set by the Commission when a risk is proportional to the actual or perceived risks, is product specific and is only temporary. France took action regarding condoms, breast implants and animal tissues, and had an open inquiry into electrical safety; the United Kingdom took action in regard to Class III implants. Fifth, and lastly, home-country control governs enforcement and implementation. Member states have ample discretion to organize implementation as they see fit, which means that in most cases they decide on the basis of a legacy of their pre-existing administrative and regulatory

Table 3.2 Medical device issues and member state sovereign powers

Clinical investigation/evaluation	Unregulated medical devices
Labelling	Advertisement/promotion Professional and lay users
Medical institutions	Reimbursement (NHS or SHI)
Post-market controls and surveillance	Price-setting (NHS or SHI)
Distribution	Evaluation (NHS or SHI)
Installation	Notification/registration for placing on the market
Vigilance	

ideas and practices. Table 3.2 provides a summary of policy issues over which the member states retain control.

EU ground rules are not tailor-made to fit each category of highly different product ranges as under the *old approach*. However, to allow for the unique characteristics of medical devices, exceptions to this five-step legislative format were made and extra - and largely medicalized - articles were added. The drafters of the EU directives incorporated clinical investigations and, after 2001, clinical evaluation into the essential requirements as follows: the utilization of medical devices must not compromise the clinical state of a patient; medical devices must achieve the performances indicated and stated by the manufacturer; and secondary and undesirable effects must constitute an acceptable risk based on the state of knowledge. Risk analysis should identify and anticipate the hazards of medical devices, and estimate likely risks. Whatever method is used to obtain the CE mark, the manufacturer is responsible for risk analysis and associated documentation.¹

As already noted above, the IVDD was delayed by eight years (Altenstetter 2002). However, the European Parliament did not delay it simply as a show of political force. In recent years, European parliamentarians from a wide spectrum of political groupings have become increasingly concerned about health and consumer protection issues and health risks arising from unsafe food, including salmonella in eggs and poultry. The single most important crisis, which set off intense debate in all political arenas and particularly in the European Parliament, was the BSE, or variant Creutzfeldt-Jakob, disease scare. The risks associated with BSE and similar transmissible spongiform encephalopathies were of great concern to consumers, health advocates, scientists and policy-makers, as well as farmers, industry leaders and distributors. After heated debates, the European Union banned specific risk material derived from bovine, ovine and caprine sources in order to eliminate any risk associated with such material entering the human and animal food chains. The implications for the medical device industry were clear, since it uses such material in manufacturing. Stearic acid derivatives are used in the processing of PVC, polyamide, polyester and other plastics, which come in contact with

a patient's body and organs through, for example, the use of surgeons' gloves.

For a decade now, controversy has raged in EU institutions over regulation of the use of human or animal tissues and derivatives in medical devices. The European Parliament favoured stiffer regulations in this area and supported pertinent amendments to the proposed IVDD in March 1996. However, failure to agree on the use of human tissue almost derailed adoption of the IVDD. In the meantime, France pushed for much stricter legislation in 1998. At a meeting in November 1997, the Commission and representatives of EU countries accepted the majority of France's requests, but refused the French call for a sixty- or ninety-day pre-market approval. The adoption of the IVDD was finally saved by separating the issue of human tissue from the IVD directive, providing a solution palatable to all policy-makers.

It took another five years before a draft version of a Human Tissues and Cell Products Directive, agreed upon by the European Parliament and Council, began to circulate. The consultation process was closed on 30 September 2002, and the European Parliament voted on it on 16 December 2003. National regulators from France and the United Kingdom on one side and Germany on the other, seem to have reconciled their differences; the industry, speaking through the European Confederation of Medical Devices Associations (EUCOMED 2001a, b, c), also sorted out its differences with the Scientific Committee on Medicinal Products and Medical Devices (European Commission 2001a). A major bone of contention between the member states and their opponents in industry and the Commission concerned the method of regulation. Should EU human tissue rules be developed under the regulatory guidelines for medicinal products or the medical devices regulatory regime? Alternatively, should a separate regulatory arrangement be made for human tissue products under the umbrella of the medical device regime, with a European-wide Tissue Engineering Regulatory Body (Kent *et al.* 2003)? The Scientific Committee's recommendations for further EU regulatory intervention was to end debates that had lingered on since the early 1990s.¹

From a patient safety perspective, promising yet troubling technological advances in life-saving and life-enhancing medical devices in clinical practice and tissue engineering are appearing faster than regulators, the Commission and the industry can agree on solutions. These innovations have real potential for improving patient care. Synthetic skin and cartilage are already in use; in the next ten years these will be joined by replacement parts for the human body, such as heart muscles. Predictably, demand for access to these products will rise. Yet cost may not necessarily rise with it, provided old and obsolete technologies and surgical procedures are replaced by newer, more efficacious ones. As a result of cost concerns in the past ten years, scientific assessment (evaluation) and political appraisal of technologies not only provide a new toolbox for cost-containment

policies in most European countries (*International Journal of Technology Assessment in Health Care* 2002, Special Issue) but are insisted upon by industry. The industry suggests that evaluation should provide 'timely access to up-to-date medical care, including medical devices and technologies', that healthcare professionals and the industry should play a key role, and that payers should not have 'a monopoly on the assessment process' (HIMA-EUCOMED 1999). Even when all the safeguards for technology assessment are secured, medical professionals are known to engage in 'offlabel' use of high-risk procedures. 'Off-label' use, which may harm patients, primarily concerns the medical profession.

The deciding and managing of health risks is a growing agenda item of EU institutions. They are concerned with rare diseases; revising product liability issues (Hodges 1999b); handling health data through the EC Data Protection Directive (Hodges 1999c); reviews of patient consent forms for breast implants five years after France withdrew silicone gel breast implants from the market; amending the MDD (Directive 2001/104/EC) by including substances derived from human blood and blood plasma (as distinct from human tissues) - an amendment that came into force on 10 January 2002; and many other health-related issues. Finally, a new Commission Decision on medical devices with specific risk materials was adopted in 2001 and should put an end to feelings on the part of some regulators that the earlier definition was too lax (EUCOMED 1998).

A battle between the medical device and pharmaceutical regimes may also have been resolved. A five-year review of the MDD implied that advocates for trade inside the Commission, along with those who favour integration of the medical device regulatory regime under the pharmaceutical regulatory regime, would win out. This intra-Commission conflict between the medical device unit and the pharmaceutical unit inside DirectorateGeneral Enterprise (previously DG III) influenced, if not dominated, the debates during 2000 and 2001. The conflict also mirrors the respective pressures of economic interests inside the Commission services. However, arguments based on the distinctive nature of medical devices as compared to pharmaceuticals carried the day at the EU level. The two regulatory regimes have not been merged, at least not for the moment. Almost everyone who influences final decision-making now seems to agree that those medical devices with the highest risks - for example, those derived from human and animal tissues - require stricter regulation, and that this should be achieved within the medical device regime. The umbrella MDD is considered to work well to the extent that when problems are encountered, they tend to lie in domestic implementation. As previously mentioned, stakeholders agree that implementation gaps must be resolved through better domestic implementation and better European guidelines.

Manufacturers are widely regarded by some as the only group with the necessary knowledge of medical devices. This has justified the building up of independent expertise both inside and outside national regulatory agen

cies. Yet both groups are reported to know less than is assumed, and considerable differences in interpretation and application by competent authorities, notified bodies and the industry have been found to exist (European Commission 2001c; Thompson 2000). When a shift was made from clinical investigations to clinical evaluation, and thus from a Clinical Investigation Task Force to a Clinical Evaluation Task Force following opposition from industry representatives, all three groups were found to be lacking in experience and knowledge.

Policy-making by EU institutions and rule-setting by committees

Regulatory policy on medical devices is subject to the same legislative processes and procedures as all EU action. The 1997 Treaty of Amsterdam added a new committee layer to an already highly complex multi-level system of governance by committees, also known as the 'comitology system'. Committees can be related to the Commission, the Council or the European Parliament (Maurer and Larsson 2001; Haibach, Schaefer and Turk 2001; Fouilleux, De Maillard and Smith 2001; Neuhold and Polster 2001). Decision-making by committees is nothing new: it has been at the heart of the EC's methods since as far back as Jean Monnet. Depending on the policy area, scientific advice in EU policy-making has been available through the Commission's 150 advisory committees, 60 management committees and 80 regulatory committees. Overall, the number of committees has grown at the micro, meso and macro levels of EU policymaking (van Schendelen 1998: 1-22, 277-293). The reasons for these committees' importance is that they not only shape policy, but also make, apply, interpret, evaluate and set new rules, as well as determining existing and new funding allocations (Haibach, Schaefer and Turk 2001: 11). In 1997, new scientific committees for medical products, medical devices and veterinary science were established (van Schendelen 1998; Joerges and Vos 1999; Vos 1999a, b; Joerges and Neyer 1997). The Commission now has to justify its decisions on all internal market proposals with scientific evidence (Art. 100(3)), and, given the variety of medical products, this evidence will be generated from a variety of highly differing scientific and technical fields and working groups within the multi-level committee system that exists in the medical device field.

Why bother with European committees in a study of domestic implementation? As a rule of thumb, 80 per cent of decisions on policy details are made by working groups; another 18 per cent reach the Committee of Permanent Representatives (COREPER), the diplomatic representation of the member states and, with the exception of 'historic decisions and policy-setting decisions' (Peterson and Bomberg 1999), very few end up on the agenda of the Council. Following Peterson and Bomberg's work, scholars have widely underestimated who 'shapes policy content', in

contrast to who influences 'historic decisions' or who serves as 'policy-setting bodies', namely the Council and Parliament. In Rhinard's (2000) assessment, these committees are 'non-majoritarian bodies, non-transparent, unaccountable and secretive'. Wessels (1998: 211-218) proposes seven alternative explanations for these committees' political significance, in addition to their role as shapers of policy. Committees are:

- watchdogs of the masters of the Treaty;
- integral to blocking defence by moribund nation-states;
- indicators of spillover and the shifting of loyalty;
- home to smooth technocratic problem-solving;
- part of the mega-bureaucracy plot;
- indicators of a non-hierarchical system beyond the state;
- arenas for merging administrative and political systems.

Given these political roles, Wessels suggests, committees are a **key variable** explaining EU governance as a multi-level system, and should be part of the search for a dynamic and comprehensive middle-range theory.

In Community risk regulation, much is at stake when scientific decision-making has the last word. This was amply demonstrated in the BSE crisis, when the Scientific Committee on Veterinary Medicine delivered the scientific opinion as to whether trade sanctions on British beef should be lifted. The committee was chaired by a representative from the same country against which the product ban was first imposed and then to be lifted (Matthews 1998a, b). Under these circumstances, claims of scientific independence and objectivity are questionable. In any event, a risk-averse public is as disturbed by the presence of scientific evidence as by the absence thereof, as shown in the case of genetically modified micro-organisms (GMMOs) and novel food (Landfried 1999). I agree with Joerges and Vos (1999; see also Vos 1999a, b) and others that risk regulation is both a political and a technical issue, and that it requires some democratic legitimacy, accountability and transparency.

Decision-making by committees is justified because of the complexity of issues that need to be resolved. Problem-solving can best be done by insulating decision-makers from politics. Supposedly, network members are **in** a position to search for the 'best' solutions based on current know-how and benchmarking of good or 'best' regulatory practices. Empirical data confirm the existence and workings of a similar multi-level committee system with similar tasks, functions and composition in the medical device field, to which we now turn.

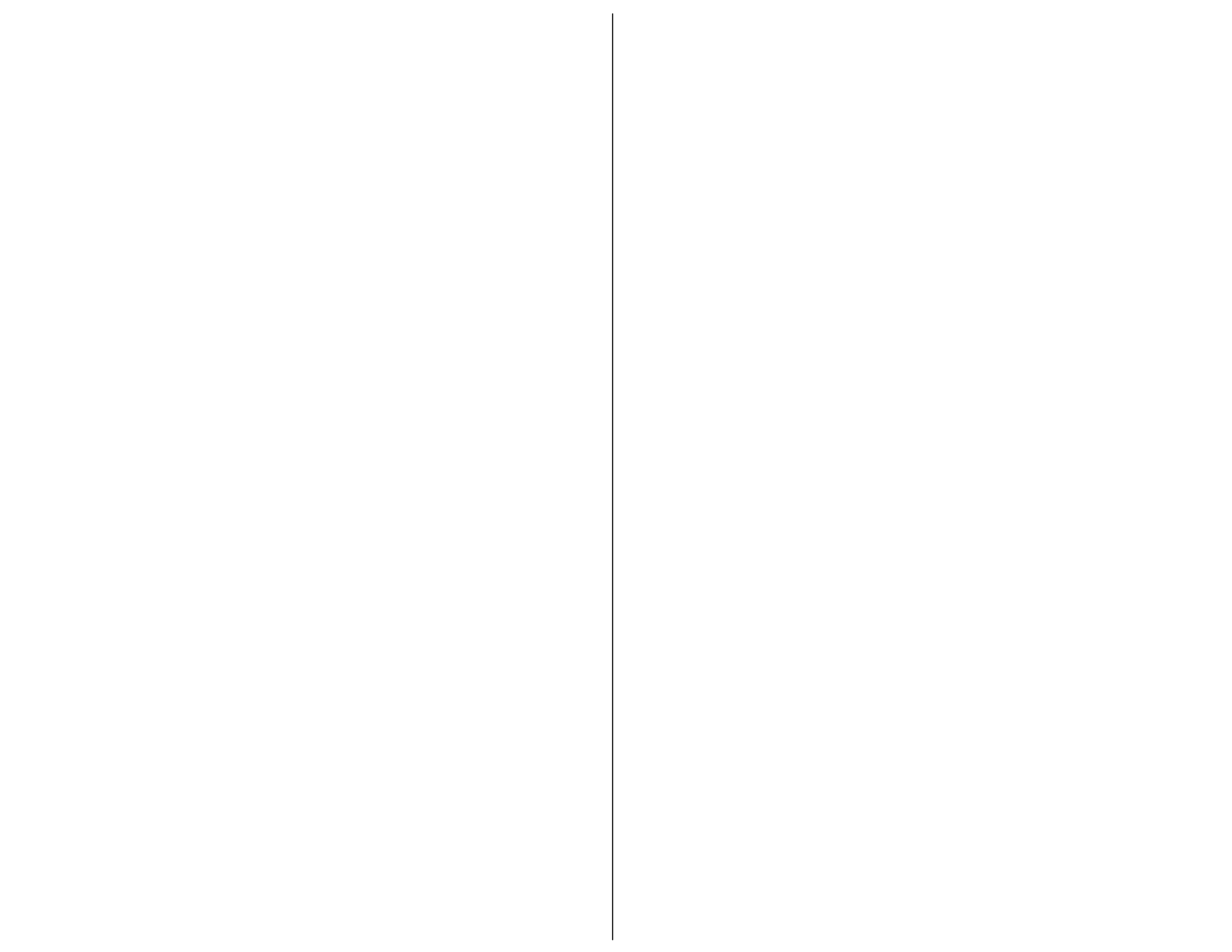
Medical device regulation by committees

The study of decision-making by medical device-specific committees is non-existent in European policy and integration studies. Yet these com

mittees decide rules and standards for safety, quality, performance and clinical efficacy for all patients in Europe and beyond. Their influence has also been growing enormously, in part as a function of highly complex issues involved in this field and in part as a means of inter-administrative cooperation and coordination across the Brussels services and national services in the interest of public health.

The complexity of problems to be resolved relating to medical devices is immense. Defining borderline products or concepts such as the 'lifetime' of a medical device or the meaning of 'shelf life', 'service life', 'regulatory life' or 'unknown regulatory life' (enforcement action) (Bennetts 2001) is not at issue. In my view, what are at stake are the following issues: are standard-setting and rule-making committees neutral and independent of lobbies and economic interests? Where do public health interests come in? Do officials work for public health or, alternatively, unhampered trade? And which national officials from which departments or offices are represented in the EU-based committees when particular kinds of issues are decided and become binding on domestic implementers? Are the most appropriate spokespersons diplomats with an interest in pursuing national interests, generalists with an interest in rules for free trade, or specialists of the medical device field who are most likely to pursue public health interests? Answers to these questions require more in-depth research. What can be pieced together is the profile of decision-making and rule-setting bodies for medical devices from a variety of sources through triangulation. My research and field notes indicate that Wessels's explanations for committee significance fully apply to decision-making on medical devices. Accordingly, in the medical device field European and national political and administrative spaces are merging in highly complex ways, as in other policy domains (Organization for Economic Cooperation and Development 1998).

Decision-making by committees must distinguish between four (soon to be five) decision-making layers. The first layer consists of two standing committees: the Committee on Medical Devices, which routinely has served as the main regulatory committee, and the Committee on Standards and Technical Regulation. In 1997 an Article 7 Committee was created, which met for the second time only in the autumn of 2001, according to a Commission source. The regulatory committee is made up of representatives of national administrations and Commission services. The Commission chairs the meeting, sets the agenda and submits issues to the committee for decision-making (Art. 2(a)) and/or 'for information or a simple exchange of views, either on the Chairman's initiative, or at the written request of a committee' (Council Decision 1999/468/EC, *Official Journal of the European Communities* 2001/C38/03, 6.2.2001). If no agreement is reached, the next step will be a decision by the Council or, the ultimate step, a procedure before the Court of Justice (Hodges 1999a). Given the fact that the Article 7 Committee met for a second time only in the



autumn of 2001, the question arises as to whether decision-makers were idle between 1997 and 2001. But in practice, EU procedures (Council Decision 1999/468/EC) allow for a formula by which MDEG meetings are conducted in two separate parts. In a general meeting, input from all parties of the MDEG group is solicited (Art. 2(b)); a second part of the meeting is declared a meeting of the regulatory committee and includes the Commission and national officials only (European Commission 2001b).

The second decision-making layer is the Medical Device Expert Group (MDEG), composed of representatives from the Commission, competent authorities, notified bodies and, recently, candidate countries. Industry is also represented through EUCOMED, the European trade association. 'Industry' in this case really refers to globally operating multinationals and their products. Although EUCOMED's membership includes small and medium-sized firms, their representatives are seldom found on the attendees list. Finally, a third layer includes seven working groups (plus several subcommittees) made up of a Commission official and representatives from industry and notified bodies. The working groups concern the following: accreditation and surveillance of notified bodies; device classification, with a subcommittee on BSE; vigilance with a subcommittee on data management/exchange; silicone gel breast implants, with a subcommittee on auditing; dental amalgam; drug/device issues, with a subcommittee on latex allergy; and, finally, meeting of notified bodies. Fourth, scientific advice on issues specific to medical devices is provided by the Scientific Committee on Medicinal Products and Medical Devices.' The Commission announced the creation of a new High Level Group for medical devices, 'allowing for consultation and mutual information between Commission and national authorities on issues in relation to medical devices' (Commission of the European Communities 2003b: 40).

Three additional features, which describe the nature of EU policy-making by committees - consensual decision-making between actors drawn from existing networks, low procedural formality and an underlying ethos of technocratic and managerial problem-solving (Rhinar 2000: 8-9) - apply to the multi-layered committee system for medical devices. First, technocratic problem-solving increases with distance from the top layer. Why should we be concerned when allegedly the best experts from industry and government make health decisions? The story told here and elsewhere suggests that there are differing views on the best scientific standards and rules, and these differences affect the safety of products. Devices can perform well but be clinically ineffective. Committees are insulated from the public, meet behind closed doors, decide in secrecy and are not held accountable to any elected body. With the exceptions of draft directives, most decisions on highly scientific and specific issues no longer appear on the agenda of the Council, the Commission or the European Parliament.

Second, a need for consensus-building on scientific advice among the major stakeholders and new institutional dynamics may mask intense political-ideological and interprofessional conflicts over risk issues that were predominant as recently as a few years ago. Yet the public remains concerned about risks to health in most EU countries and is reluctant to accept consensus-based scientific evidence, as shown by the debates in the European Parliament and its committees over the BSE crisis, breast implants, patient consent forms, or similar topics involving decisionmaking and health risk management.

Third, a focus on scientific decision-making tends to privilege the larger member states, which possess the necessary expertise and scientific capacity (Joerges and Vos 1999; Vos 1999b). This conclusion resonates with observations from the medical device field. Sources close to the regulatory process note that France, Germany and the United Kingdom were allowed to lead the process from 1990 onwards, while the remaining member states basically took a back seat behind the 'big three'. Together with Italy, the 'big three' propose, bargain, and recommend rules for action; prior to enlargement in 2004, they controlled forty votes out of the sixty-two needed for a qualified majority in the Council (Art. 205 of the Treaty of Amsterdam, previously Art. 148 of the Treaty of Maastricht). In the *in vitro* diagnostics sector the two main players are France and Germany, which usually act jointly on behalf of other countries. A similar distribution of influence by industrial interests and countries can be expected for the remaining committees relevant in this field.

In fact, the distribution of influence and power can be seen in the medical device field from EU-level committees to the global committee structure, the Global Harmonization Task Force (GHTF) for medical devices, which is concerned with global regulatory convergence. The composition of the GHTF and its four sub-committees tends to be dominated by Anglo-Saxon representatives from large multinational corporations on both sides of the Atlantic, despite efforts to rotate the chair between geographic regions. EU level working groups seem to be dominated by representatives of industries located in the 'big three' countries regardless of whether they represent native European corporations or subsidiaries of US companies. ISO and International Electrical Committee (IEC) standard-setting committees show a similar representative pattern, with national standard-setting bodies playing an important role. Data and preliminary analysis on the origin and participation of international scientific elites suggest a similar pattern; but a systematic assessment is still required (Altenstetter 2001).

The In Vitro Diagnostic Directive and domestic implementation

After having transposed directives, member states are able to organize their own methods and mechanisms for implementation. While past

research focused heavily on the AIMD, the MDD and the three crucial stakeholders - national regulators, manufacturers and notified bodies (Altenstetter 2002) - this section will focus on the particularities of the IVDD. For domestic implementation of pre-market controls, national regulators have three policy instruments at their disposal: inspection of manufacturers, evaluations, and post-market controls. Their use depends on resources and capacities, which vary significantly across the fifteen pre2004 member states. Prior to the IVDD and depending on the country, a 'piecemeal approach' to regulation existed. The oldest and most comprehensive legislation existed in Germany (1978, covering groups of products), France (1982, covering all diagnostic products), Spain (1987, covering HIV and hepatitis tests) and Italy (1991, HIV). Outside the Union, Austria and Switzerland had also implemented regulation (in response to AIDS). According to an industry insider (Suppo 1997; 2000: S4.1), diagnostic companies reacted in 'patchwork fashion' to the 'patchwork nature of regulation'.

The IVDD follows the legal architecture of the AIMD and MDD. However, it contains a number of provisions and complex annexes that make it a highly unusual *new-approach* directive in at least three ways: rules and procedures are quasi-harmonized at the European Union level; registration and notification requirements, which are normally seen as trade barriers, are introduced; and, similarly to pharmaceutical regulation, common technical specifications (CTSs) are established for evaluation, reevaluation and batch verification. While the IVDD covers heavy equipment and computer laboratory systems and in vitro diagnostic (IVD) products, the following comments apply to in vitro products only. Typically, IVD products are single-use devices; when they fail to perform as intended, they constitute unacceptable health risks and mislead those carrying out analysis and diagnosis. Unlike essential requirements for the AIMDD and the MDD, CTSs make the evaluation of clinical and analytical data mandatory; reliance on performance as intended by the manufacturer under the previous two regulations is considered insufficient. In mid-2002 a consensus on draft CTSs for high-risk devices emerged among the major stakeholders. In the past, the industry and the Commission refused special requirements for IVD products. CTSs were pushed by national regulators led by France with the support of Germany and other countries (*Regulatory Affairs Journal (Devices)*, January-March 2002: 37).

Power-sharing between the European Union and member states leans towards the former in the implementation of the IVDD. In this case, member states are not entirely free to choose methods of implementation, as they are under the MDD and AIMDD. Moreover, the IVDD has produced spillover effects on medical institutions, laboratory medicine, diagnosis and analysis, and free-standing laboratories, thus raising fine legal points probably understood only by a few legal specialists from the United States and Europe. Delays in implementation are normal events and not

peculiar to medical devices. The IVDD was adopted in December 1998, eight years after a first draft was discussed in the European Union. It was to be transposed by 7 June 2000, and after December 2003 only CE-marked IVD medical products were to be placed on the market. Yet most countries did not make the deadline, which was postponed until 6 June 2000 (*Regulatory Affairs Journal (Devices)*, February 2000: 45). Table 3.3 illustrates IVDD implementation status as of August 2001.

In vitro diagnostic products were grouped into four categories according to the risks to public health and/or patient treatment:

- general products;
- self-testing items;
- Annex II List A, which includes, among other things, test kits for rubella, toxoplasmosis, phenylketonuria and blood glucose;
- Annex II List B, which includes test kits for HIV, human T-cell lymphotropic virus (HTLV), hepatitis, and some blood grouping products, including those used to test donated blood.

Data generation, collection, analysis and evaluation of IVD products follow the same four categories. Unlike previous national regulation in a few member states, the IVDD covers not only reagents, but also automatons, robots, computers, etc. The inclusion of entire laboratory systems in the scope of the Directive led to enormous uncertainties among all parties involved for the period from 1999 to 2001. Moreover, when the IVDD was adopted, no one really knew or understood the meaning of the above lists. Legal consequences ensued, depending on whether transposition was 'deliberately' or 'accidentally' out of line with the scope of the Directive (Hodges 1999a). Delays in designating ten notified bodies specifically accredited for handling conformity assessment procedures and quality control of IVD products added to the uncertainty.

IVD products are high-risk products and as such require registration and notification of manufacturers, authorized representatives, distributors, and products. In the United Kingdom, manufacturers must register with the Medical Device Agency (MDA), which in 2002 was merged with the Medicines Control Agency to become the Medicines and Healthcare Products Regulatory Agency (MHRA). In France they register with the French Agency for Health and Product Safety (AFSSAPS), and in Germany with the Federal Institute for Drugs and Medical Devices (BfArM). Registration in other EU countries can also be with a regulatory agency located in the same area as the head office of the company. In the event of problems with IVD products, this agency serves as a lead agency, even though the products may have been distributed in another country. National regulators can, but need not, require registration of products prior to their launch on the market. When they regulate, they must not exceed EU provisions. Manufacturers must obtain a

of the ten notified bodies specifically accredited for IVD products. Member states have discretion to impose additional restrictions, and have used this opportunity in many of the policy areas listed in Table 3.2. For biotechnology firms, safety reporting regulations are more challenging than for other medical device manufacturers. Regulations differ, depending on the product - drugs, biological entities, devices, or biological products - as well as the country, and on whether reporting refers to clinical investigation (now evaluation) in the pre-market phase or during postmarket surveillance (Kingma 1998). All in vitro diagnostics share one experience: the speed of technological innovation tends to outpace the speed of regulation even faster than with other medical devices.

For the recall of products, the IVDD stipulates that where a member state requires medical practitioners, medical institutions or the organizers of external quality assessment schemes to inform the national lead agency (or, in EU legalese, so-called competent authorities) of any incident referred to in the directive's first paragraph, it must take the necessary steps to ensure that the manufacturer of the device concerned or its authorized representative is also informed of the incident (Art. 11(2) of the IVDD). The exact definition of 'manufacturer' (Articles 1, 2f), however, is of real concern to the industry. The IVD industry is extremely complex: not only do companies purchase components from other firms, but sometimes the entire product is made by another company. Regulators in countries that have already developed some form of IVD regulation are well aware of these hurdles to determining accountability for manufacture (Suppo 2000: S4.12).

The IVDD differentiates between 'placing on the market' and 'putting into service'. The latter can have several meanings and, depending on the meaning, invokes the responsibility of different actors. A product can be 'put into service' after installation of any special equipment, upon delivery at the hospital, only at the moment of use, or even when products are put in a catalogue or advertised on the Internet. 'Homebrewed products' were exempt from the IVDD under pressure from lobbying by UK microbiologists, who feared that the products they prepared in laboratories would fall under the scope of the IVDD (Suppo 2000: S4.12). The 'big two' in the IVD field did not object, since the issue posed no threat to their industries. However, in-house manufactured products ranging from homebrewed products to the sterilization of single-use devices for multiple use in hospitals may come under the purview of EU regulation in the future. On 10 May 2001 the European Court of Justice ruled against a Danish hospital whose in-house manufactured product caused medical harm. This ECJ ruling introduced a requirement whereby all such in-house manufactured products may come under the product liability directive as amended (85/374/ECC; Clinica June 2001: 962).

Source:
Note
a The f

Reporting procedures

Since there is no social science information in this field, in order to understand problem-oriented implementation we have to rely on industry sources. If the issues addressed in Table 3.4 are not resolved, they can pose serious health risks to patients and users, particularly in countries that have had no regulation at all. Inconsistencies in terminology and differing interpretations of the reporting requirements by national regulators in each country are reported. The information appears credible and plausible.

National variations across member states

The objective of EU regulation is to secure uniform interpretation, application and implementation in all states of the European Union. Yet there is a paradox. Although member states are more restricted concerning implementation of IVD products than concerning medical devices, uniform reporting of accidents and near-accidents in the European Union has a long way to go (Altenstetter 2003b). The European Diagnostics Manufacturers Association drafted a European form for use; however, national forms were developed instead in Sweden, the United Kingdom, Belgium, Denmark, France, Germany and Spain (Brown 2000). France, Germany and the United Kingdom, which regulated IVD products prior to EU regulation, continue to use their own routines, data banks and forms for reporting accidents and incidents with these unusual products. For example, the British MDA required medical devices used in clinical investigations to be subject to reporting requirements; it thus went beyond the scope of the non-binding EC Vigilance Guidelines. In addition, the

Table 3.4 Experience with reporting of adverse incidents due to IVD products

- The information available, while considerable, is of poor quality.
- Competent authorities (CAs) demand early answers when information is not available or relevant; redundant reporting requirements lead to redundant queries from CAs.
- Some CAs do not hear appeals from manufacturers.
- Independent experts are unavailable in some sectors, and sometimes only available to CAs.
- Some overreaction to problems (e.g. breast implants).
- Directives use inconsistent terminology and exclude important requirements, including the following:
 - 1 The AIMD has no notification requirement in case of incidents involving clinical trial devices. •
 - 2 The IVDD has no undertaking requirements when Annex V (Type testing) is combined with Annex VIII (Production Quality Assurance).
 - 3 The EC Vigilance Guidelines have no legal status.

MDA requires observance of product-specific guidelines for breast implants, heart valves and joint replacements, as well as guidelines for recalls and post-marketing surveillance of hip joints.

The German Ministry of Health has extended long-established practices to require a safety officer in hospitals under hospital legislation and regulation of medical devices and IVD products. A safety officer must be based in Germany to represent a manufacturer, importer or authorized representative. Germany intends to report adverse incidents on German forms, in addition to those included in the non-binding EC Vigilance Guidelines. Similarly, French regulation requires a vigilance correspondent to represent a manufacturer and its authorized representative. AFSSAPS also requires French forms in addition to those recommended for use in the EC Guidelines. AFSSAPS requires reporting, in French, of serious injury or death without delay, contrary to EU regulation, and nearincidents on a quarterly basis.

While it may seem odd to outline these highly technical details of the regulatory process, they are not irrelevant for policy. Instead, they point to important observations about the member states: a strong legacy of past administrative practices; a desire to control path-dependent regulatory mechanisms and processes; a lack of trust across the member states; a desire to educate their own target groups in the health sector; and a preference for their own tools of compliance, enforcement and problem-oriented implementation. These circumstances hint at the difficulty of systematic cross-national research on reporting injuries, death or neardeath: data are not comparable, and researchers are faced with complicated methodological and definitional problems (Altenstetter 2003a, b). In the Commission's words, 'statistical data on reported cases are extremely heterogeneous', ranging from comprehensive reporting by France and the United Kingdom, primary reliance on reporting by manufacturers in Germany, to very limited reporting in most other countries, as documented in Table 3.5.¹⁰

The European regulatory data bank for medical devices, EUDAMED, follows legal and administrative categories for registering incidents, accidents, deaths, and recalls of medical and in vitro devices. In November 2001 the data bank was reviewed by the MDEG. In the Commission's view, EUDAMED is 'not captive' to industry, is 'user-friendly' and reflects 'state of the art' knowledge (Brekelmans and Nonneman 2000). But when the juror serves as jury, the situation is murky. On the other hand, a case for a centralized regulatory data bank at the EU level can be made; its advocates see virtue in streamlining information generation, collection and assessment. In contrast, the 'big three', while not opposed to EUDAMED, see advantages in a decentralized regulatory and information system that they control.

The suggestion that national administrative practices and arrangements are losing ground under the pressures of Europeanization and even

	Manufacturer reports received	User reports received	Manufacturer reports received	User reports received
ZP	~rno~m l ~ /~MN°~°	"MONON(⇒I-01 N-4 ~O W) OC) 00 '~	~D44 ~ ~ ON	1 A Cd ^q -N M\$ 'lt
ZQ	Z z z	h 1	ON ~ I ,t 1-4 OON m b ⁽⁵ r-.-/N	0
ZR				
ZS				
ZT				
ZU				
ZV				
ZW				
ZX				
ZY				
ZZ				

europa.eu.in/comm/enterprise/medical_devices/ca/vigilance_

Source: Draft HS statistics.pdf.

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globalization of medical device regulation may be premature. By examining the items on the GHTF agenda, we can document global and regional convergence of regulatory goals, strategies and ideas about quality, safety and performance standards, and about evaluation in the case of IVD products. On the other hand, Commission data (2003b) and 'grey' literature report on the divergence of regulatory arrangements and procedures across the 'big three', and the twenty-five EU member states (Altenstetter 2005). Rather than diminishing, the importance of the 'regulatory state' is increasing under the cross-pressures of global and regional regulation and domestic healthcare reforms. Instead of regional convergence, national variations will further increase after enlargement in 2004.

The power-sharing arrangements between the EU and member states do legitimize variations in regulatory responses to medical technologies and health risks. In addition, the principle of subsidiarity further encourages not only the coexistence of European and national initiatives but also various responses. Below the national level, the medical device regulatory regime, which consists of four sub-regimes, features many more differences in implementation and outcomes than are already identified in a single country case at the level of macro and meso structures (Altenstetter 2003a).

Concluding comments and lessons

With the passage of the three medical device directives, most European countries have been asked for the first time to control the market access of medical devices, engage in post market surveillance and establish a vigilance process

particular, one can observe a process of differentiation, toughening and reclassification of the highest-risk products, such as breast implants, heart valves, stents and joint replacements. Stakeholders, in particular in the IVD field, have rallied behind higher protection levels in the interest of public health. They have favoured the harmonization of EU rules on the one hand while upholding national preferences on the other. France is submitting all medical devices to evaluation procedures similar to those that apply to pharmaceuticals in order to prove that new products have higher benefit/risk ratios than older ones. If a product or procedure is found not to have an added value when compared to existing procedures and therapies, it will not be included in the national benefits catalogue and reimbursed by public payers. British regulators share similar views. In the past decade both countries have become veterans of using technology assessment to aid decision-making for new breakthrough technologies. A laggard for close to a decade, Germany has now endorsed the view that the litmus test of breakthrough therapies is whether they show higher benefit to risk ratios than established products, therapies and surgical procedures. Though the German enterprise of technology assessment is small and capacities are rather limited, it was aggressively pursued by the minister of health for disease management programmes in time for the federal elections in September 2002. In the future the Commission (2003b) will insist on more harmonized implementation throughout the member states.

In fact, there is a considerable gap between the rhetoric of assessing medical devices to aid decisions on including new therapies and procedures in national benefits catalogues, de-listing ineffective therapies and procedures, and substituting clinically effective and possibly cost-effective therapies and procedures. In all three countries, risk-benefit analysis and technology assessment in healthcare, while presented as objective science, are used for decisions on coverage, reimbursement and price-setting by the British National Health Service and the French and German statutory health insurance programmes. This view may contrast with those of advocates of healthcare technology assessment (HTA) and evidence-based medicine. Yet even advocates of rigorous evaluation as a precondition for market authorization - that is, obtaining the CE mark - admit that the process will always involve problems, perhaps even unsolvable ones. If central findings of technology assessment and recommendations through practice guidelines are relevant for national decision-makers only and do not trickle down to clinical practice and patient care, they may have little more than symbolic value despite being costly. But normative declarations cannot be equated with empirical evidence. Whether a shift from rhetoric to reality has actually occurred needs to be documented.

Most regulators and industry leaders agree that the process and procedure for market access - that is, CE-marking - need improvement, as do post-market surveillance and adverse incident reporting in each member state. National regulators agree on grand goals, but differ on much more:

how to strengthen oversight and enforcement over certification bodies; whether and, if so, to what extent they can rely on product approvals from third countries; and whether reporting requirements should include as large a target audience as possible, including medical institutions, users and patients, or only manufacturers, as is the case in Germany. However, all three agree on stricter harmonized European standards (EN) and international standards (ISO), as well as common technical specifications (CTS) for the manufacture of IVDs.

The European Commission and the industry dislike unilateral national measures. Member states do not hesitate to engage in their own proactive and reactive strategies when they consider them necessary. By the same token, member states support the development of European rules, provided they leave room for national rules and action. Over the past ten years, industry leaders and policy-makers from the three countries have pushed hard for the establishment of a medical device regulatory regime distinct from the entrenched regulatory regime for pharmaceuticals. Borderline products were the exceptions. With dramatic medical advances such as tissue engineering being made during this period, another layer of reality is catching up with the key actors. However, the fourth directive on human tissues and cell products is expected to offer clarity and end uncertainties. Eventually, the sectoral regulatory regime for medical devices will consist of four sub-regimes, each with distinct requirements and mechanisms. In a decade, the learning curve across all stakeholders has been considerable. There remains a widely shared dilemma: knowledge production and innovations outpace appropriate regulatory responses.

Several lessons emerge from this research on medical device regulation. First, the research speaks of the complexity of the relationship between European law and national law, and between emerging highly specialized European and national case law pertinent to medical devices.

Second, it points to two factors impacting upon national policy autonomy in the health field: autonomy is being eroded by the implications of singlemarket directives; and, through separate processes, autonomy is expanding at the same time through benchmarking for 'best regulatory practices' across a multi-level committee system that spans the global, transnational and national levels and allegedly includes the world's best experts.

A third lesson is that the pre-eminence of domestic institutions, administrative capacities and national preferences are characteristics of regulatory practices in medical devices.

Fourth, to the extent that European health policy exists at all, it is fundamentally linked to the European regulatory policy rooted in the creation of a single market, which produces many cross-cutting issues and effects on healthcare systems. The regulation of medical devices has involved considerable learning through trial and error, correction and adaptation as well as feedback of experience, and information-sharing and new insights have been put to work over a ten-year period.

A fifth lesson is that regulation linked to market creation does not have to be a race to the bottom. In fact, global and regional regulatory harmonization of medical devices has *not* lowered standards. Rather, the quality, safety and performance standards and the evaluation, re-evaluation and batch verification of IVD products have raised the safety threshold in the European Union and beyond. Finally, despite a growing body of literature on healthcare in the European Union, we still have a shortage of systematic empirical data and information on the effects of the single market and European regulations on healthcare systems. While the OECD data bank has advanced cross-national research in the health sector considerably over the past two decades, it has not facilitated systematic comparative analysis of medical devices and innovations, post-marketing surveillance or medical vigilance systems; nor has the European regulatory database, EUDAMED. We still do not have systematic information on reimbursement, pricing and price-setting, purchasing practices, site planning of heavy medical equipment, the cost of training of highly skilled staff, equipment utilization, or equipment maintenance and servicing over and above what was known in the early 1990s (Banta *et al.* 1994). The conditions under which information between investors, clinical investigators and vendors are transferred are well-kept secrets, as is information on test sites for medical devices and sites funded by medical supplier firms. How healthcare reformers in most European countries can achieve the savings they promise by building bridges between local delivery sites and distributors, vendors and purchasers, in the absence of information, remains a mystery.

Using previous research as a guide has meant that an agenda for future research emerges. In the health sector the *politics of policy-making* framework has been favoured over other approaches to explain national developments in health systems and path-dependent interpretations of policy formulation and adoption. Yet in domestic implementation studies, pathdependent developments and structures are even more significant. 'Pathbreaking' reforms that are enacted may be stopped short, delayed, altered or subverted in implementation, and this is true regardless of whether we consider the implementation of transposed EU directives or of domestic legislation. Also, path-dependent explanations in one sub-sector do not explain developments in another sub-sector and are often insensitive to sectoral variations in implementation. For example, who would have predicted that the medical device regime would consist of four directives which, as a minimum, can entail up to four distinct institutional arrangements for implementation in a country?

To understand the effects of Europeanization on healthcare policies, we need to complement the *politics of policy-making* framework with insights from comparative public policy, EU governance and European integration studies. Four research traditions in particular may be helpful in this regard: the national adaptation framework (H6ritier *et al.* 2001); the liter

ature that attempts to come to grips with the various facets of Europeanization (Bache 2003); a policy implementation framework that integrates a top-down and a bottom-up perspective and focuses on organizational actors and interdependent multi-organizational systems and networks rather than hierarchies; and sectoral and issue-oriented studies specific to a policy sector. Studies on economically significant sectors should be supplemented by studies on politically sensitive sectors such as pharmaceuticals, medical products and food safety. All four traditions relate to the multi-level, multi-unit and multi-actor nature of governance and networking; single-actor systems with a clear locus of responsibility and accountability do *not* exist. Empirical evidence for the merging of European administrative space and national space (OECD 1998) can only result from a plurality of approaches. Though they are changing, national structures, administrative arrangements and procedures remain firmly in place.

Notes

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- 1 Several additional directives are relevant for the enforcement of the three main directives. The most recent directives are Directive 2003/63/CE amending Directive 2001/83/CE; Directive 2003/32/CE of April 2003 concerning the use of tissues of animal origin; and Directive 2003/12/CE on the up-classification of breast implants. Other relevant directives include the Clinical Trials Directive (2001/20/EC), adopted on 4 April 2001; the so-called Blood Directive (2000/70/EC), adopted on 23 October 2001; and the much earlier Personal Protective Equipment Directive (89/686/EEC), adopted on 21 December 1989.
- 2 For details, go to <http://www.europa.eu.int/rapid/start/cg>/guesten> (accessed 12 July 2003).
- 3 Dr David Jeffreys, Head of Devices Sector, MHRA (UK), speaking about regulatory reform in Europe at the AdvaMed International Conference in Washington, D.C. on 9 September 2003 (<http://www.AdvaMed.org>, accessed 10 July 2003). The European Parliament adopted a fourth directive on Quality and Safety for Human Tissues and Cells on 16 December 2003. This topic was initially on the agenda of medical device regulation in the early 1990s but could not be resolved as a result of major disagreements between France on the one hand and the Commission and other member states on the other. Human tissues and cells were initially covered by the IVDD adopted in December 1998 but had to be dropped to secure the passage of the IVDD.
- 4 http://www.europa.eu.int/comm/enterprise/medical_devices/tissue/index.htm (accessed 12 July 2003).
- 5 Contrary to common understanding, CE does not stand for the French term for 'European Community'; rather, it means 'Conformity with European regulations and directives' (*Conformité Européenne*).

- 6 The *old approach* (1969-1984) introduced five different methods of harmonization: total harmonization; optimal harmonization; reference to standards; conditional recognition of approval; and mutual recognition of approval.
- 7 Risk assessment, a risk management process and a risk-benefit analysis are preconditions for market authorization. Risk assessment may be described as 'a scientifically based process comprising four steps: hazard identification, hazard characterization, exposure assessment and risk characterization'.
- 8 This directive is the subject of a cross-national project on Tissue Engineering and Governance (TERG) operating out of the University of Cardiff and including Alex Faulkner, Julie Kent, Ingrid Geesink and David Fitzpatrick.
- 9 For a list of the Committee's Opinions, go to <http://europa.eu.int/comm.foodfs/sc/scmp/index.en.html>.
- 10 For a record on reports by competent authorities, go to http://www.europa.eu.int/comm/enterprise/medical_devices/ca/notif_report.htm (accessed 12 August 2003).

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