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Multi-level Implementation Networks: The Case of Medical Devices and Patient Care.

Draft: Work in Progress

By

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Introduction

Regulatory integration is a central aspect of European integration and a central theme of ECSC's Sixth Biennial International Conference. Yet the debate about integration largely avoids a fundamental question: who *translates the intent of EU decisions into reality*? Who disposes of the capacities—organizational, professional and scientific, financial, information and communication—necessary for implementing EU regulatory policy? Legal scholars closely follow changing regulatory requirements under global and regional regulatory regimes (Columbia Law School 1999; Devuyst 1999). Research in political science is beginning to address these issues, for example, research on the role of European agencies (Shapiro 1997; Majone 1997; Kreher 1997; Dehousse 1997); national policy adaptation (Heritier 1997) and enforcement and compliance with EU directives (Haas 1992; Menindreneou 1996; Siedentopf and Ziller 1988).

The regulation of medical devices (goods), their use in clinical practice and in particular the use of human and animal tissue in patient care raise complex issues which open a debate at the intersection of other debates over: policy, professional and scientific issues, ethical issues, management and governance. From a medical and humane standpoint, stricter rules for medical devices, health surveillance and medical vigilance in health sites are the right and desirable outcomes. The intention is to ensure the use of safe products as a *sine qua non* of any advanced health care system. However, even in this area, a wide gap exists between good intentions and actual outcomes. A recent report of The Institute of Medicine on To Err is Human. Building a Safety Health System is a compelling testimony of these concerns for patient safety.¹

As a result of these developments over the last few years, awareness is growing everywhere that medical, environmental and food risks to health need to be managed better than they have been in the past, and that the man/machine interface can be dangerous to our health. Yet consumers, providers and policy-makers usually "take for granted" (Baldwin *et al.* 1998) that the medical products we purchase or those used in medical procedures and patient care are safe, of high quality and perform well during the entire life-cycle of a product, irrespective of the country of origin. Do we inquire what is done when incidents with medical devices occur? Who must or can report them? Who is responsible: the product or the professional user who may have committed a human error? And, finally, who, if anybody, investigates accidents with medical products?

For most humans and social scientists the regulation of medical devices is an exceedingly obscure topic. Yet it raises salient policy issues while challenging theory and analysis in more than one subfield in political science.

¹Among other key issues the report explores: "why do errors occur? what error reporting systems exists, how are performance standards set? what are the expectations for patient safety? what kind of reporting system should be required: voluntary or mandatory? how can safety in healthcare organizations be assured?"

In practical terms, however, multi-level decision-making systems (Scharpf 2000) reflect two trends: one is the story of globalization and regionalization, the other is the story of increasing complexity of scientific and technical issues involving medical and bio-engineering knowledge and highly specialized skills as well as a limited problem-solving capabilities of national decision-makers. Yet only a few possess the necessary knowledge and the required scientific skills. In consequence, a restricted circle of decision-makers produce consensus-based knowledge in the medical device field acting under conditions of on-going changes and a great deal of uncertainty.

Research and Data Collection

One objective of this paper is to understand the nature and role of policy networks and multi-level regulatory decision-making systems in the field of medical devices, their composition and activities in a global context. The emphasis is on reconstructing the basic structure of the actors involved in multi-level regulatory processes rather than a systematic examination of the structure of each network type.

This paper grows out of an on-going cross-national research project entitled *Regulatory Regimes in Transition: The Medical Device Sector and Patient Care*.² In 1995, it started out as an exploration of the implementation of regulatory policy specific to medical devices in the European Union, focusing on two levels of rule-making and rule-application and drawing a distinction between the formulation of *policy* and *operations* to carry it out: 1) the EU level of rule-making and implementation, and 2) the level of national and subnational implementation. Through focused case studies of domestic implementation in France, Germany, and the United Kingdom, the cross-national comparison has intended to identify similarities and differences in the implementation of European legislation, and shed light on the strengths and weaknesses of their responses at both the *policy* and the *levels of implementation* from national to local.³

The project is based on three premises. First, following a well established canon of comparative policy research I assume that actors' perceptions and actions differ at the *policy* and the *operational* levels. Second, as an applied policy researcher, my starting point is this. European and global public policy outcomes, like domestic outcomes, are shaped by the attributes of the

² By regulatory regime, this paper follows the definition proposed by Hollingsworth, Schmitter and Streeck (1994, p.4). "A regulatory regime covers the totality of institutional arrangements—including rules and rule-making agents—that regulate transaction inside and across the boundaries of an economic system."

³ Over 40 interviews with relevant actor groups were conducted in the UK and about 100 in France. In Germany, the field work has not progressed beyond data collection on the formal mechanisms for enforcement and compliance (Altenstetter 1998). Interviews with members of the relevant policy communities will start in 2001/2002.

policy domain(s) and the industrial sector(s) of which they are a part, and by the substantive issues at stake. Finally, the project is anchored in five bodies of literature, which offer alternative explanations and provide overall guidance for data collection and field work: (i) the literature on regulation, (ii) domestic implementation, (iii) European integration and EU governance; (iv) historical-comparative (empirical) institutionalism and, last not least, “epistemic communities” (Haas 1992; Richardson 1993). Rather than offering a detailed discussion, what is of interest is the complementarity among them.

(i) Theories of regulation (Dyson 1992a and 1992b; Baldwin et al. 1998; Baldwin and Cave, 1999) focus on the influence of actors, the locus of power and the role of institutions. They also draw attention to the normative values, beliefs and attitudes that underpin the interaction of market, state and third-party self-regulatory actors. The medical device sector shares similarities with other industrial sectors. “Regulatory policy (as any other policy), writes Reagan (1987: 6), results from the interplay of goals, facts, and values.”

Dyson identifies four characteristics: regulation is (i) a cultural phenomenon; involves (ii) a formal, institution-based mechanism which unfolds in (iii) a political and coalition-based process; and is best described as (iv) a learning process of new experiences with regulation within policy networks of highly professional actors. Learning involves learning about the goals of regulation, the regulatory instruments adopted to achieve these goals, the rules governing the regulators and the regulated, and adaptations to new rules and changes in a larger regulatory context beyond the medical device sector. Dyson writes, “regulations are the product of the characteristics of complex policy networks and coalition activities which reflect an ability of policy actors to formulate and choose regulation actions and to make use of ideas to guide the development of regulation.”

ii) The implementation of EU directives involves issues of enforcement and compliance with EU law (Hanf 1982). Legal intentions need to be converted into implementable instruments and strategies. Theories of implementation point to five analytical dimensions which come into play and are considered important: (i) policy content; (ii) institutional context; (iii) capacities to carry out policy; (iv) commitment of actors to the regulation, and (v) coalitions and clients (a coalition-based process) (Najam 1995). One research task is to identify those factors that facilitate the implementation of safety, quality and performance standards—prerequisites for market authorization—and those factors that impede enforcement in each country. In other words, the key issue is how France, Germany and Britain adjust their previous regulatory practices to the new European regulatory requirements.

Following the conventions of domestic implementation research I could examine global and regional regulatory integration from a top-down and a bottom-up perspective. In practice, however, if regulatory integration is understood as a dynamic, reiterative political process characterized by feedback and learning among multiple actors across several policy and operational levels, specifying the top and the bottom is arbitrary. Clear demarcation lines between decision-making levels cannot be drawn *de jure* and *de facto*, given overlapping membership of

key players in several decision-making processes and unfolding at different levels.

(iii) Theories of European governance (Marks *et al.* 1996; Kohler-Koch 1996) and domestic governance provide guidance of how to view multi-level decision-making systems and policy networks, embedded as they are in the EU governance structure and in particular the committee structure evolving around medical device regulation. Seen as a micro-cosmos of the larger EU committee structure or “comitology,” however, the committee structure in the medical device sector also has a few particularities.

Policy networks are direct responses to the transformations in governance (Kohler-Koch and Eisinger 1999). These transformations are observed domestically, in the EU multi-level governance system and internationally. Kenis and Schneider (1991:41-42) provide a useful framework the current work as for past research (Altenstetter 1994).

“A policy network is described by its actors, their linkages and by its boundary. It includes a relatively stable set of mainly public and private corporate *actors*. (in original). The *linkages* between the actors serve as communication channels and for the exchange of information, expertise, (p.42), trust and other policy resources. The *boundary* of a given policy network is not primarily determined by formal institutions but results from a process of mutual recognition dependent on the functional relevance and structural embeddedness.”

(iv) Historical and empirical institutionalism is useful in two ways reinforcing many points highlighted above. First, when examining the role of the leaders (Britain, France and Germany) in shaping the content of regulation and the strategies it is apparent that representatives from each country have brought fixed ideas about quality, safety and performance of medical devices to the negotiating table. Rooted in administrative traditions and professional traditions ranging from law, medicine to engineering, differences in perceptions are impressive. Second, without allowing for “path-dependent” influences on domestic implementation, I see little possibility to explain the outcomes of domestic implementation in each country eventually.

(v) The concept “epistemic communities” is borrowed from IR (Haas 1992; Richardson 1993). “Epistemic communities” are key for an understanding of policy networks operating within multi-level decision making systems. Members of policy networks are said to share similar values (“normative and principled beliefs”), shared “causal beliefs”, “notions of validity” (value-based) and they participate in the same “policy enterprise.”

Epistemic communities and domestic implementation networks share one characteristic. In explaining epistemic communities Haas refers to the concept “loose coupling” and “loosely coupled structure,” as Elmore (1978: 165) does for domestic implementation. According to him, “[a] policy sector usually consists of a collection of many diverse governments, bureaucracies, courts, public and private interest groups, local delivery systems, clients, and individual actors whose complex interaction are often hard enough to uncover, let alone describe...The interactions

in such sectors as education, health...are sometimes fluid, frequently chaotic, and always conflictual. Nonetheless, policy sectors typically have tacit operating rules of the game, established roles, routinized procedures, and reasonably stable conditions. These enduring patterns of behavior can be called a *macro-structure*.” Loose coupling stands for two ideas: (1) “each organizations has its own problems, perspectives , and purposes that reflects is particular structure and culture, and (2) each organization acts more or less autonomously within the overall macro-structure of the sector.”

Networks of actors are known to produce new and consensus-based knowledge for use in setting regulatory requirements. Yet, they also suffer from a built-in weakness. Scharpf (1989) writes:

“Unanimity protects vested interests in existing regulations and government services, regardless of any changes in external circumstances or political preference that would preclude contemporary agreement on these same measures.” Thus, once we move from single-shot decisions to ongoing decisions systems, there is no reason to associate either efficiency or libertarian values with Unanimity or with contractarian institutions: They will perpetuate ‘involuntary’ governance and socially inefficient ‘political rents’ by protecting past gains of ‘distributional coalitions’ (Olson, 1982) against policy change). Thus, in ongoing decision systems and under conventional assumptions about the motives of decision-makers, Unanimity is likely to be associated with a growing body of public policies that are illibertarian and substantively inferior to those that might have been obtained under hierarchical or majority decision rules.”

Does this characterization apply to multi-level decision-making and implementation in the field of medical devices? It all depends on who is answering the question and from which perspective. We will know when the empirical part is completed. But field work already has turned a two-level analysis into a four-level analysis. And the “long way from policy to operations” (Williams 1980) under globalization pressures is getting longer and running the whole gamut from global to local and the reverse.

Tables 1 through 3 below provide the evidence which shows that regulatory transformations in this sector have been under way at four levels: global, regional, national as well as sub-national/local.⁴ Policy elites from the industry and the government sector, other high-level policy makers, in addition to scientific experts, tend to dominate these policy networks. They serve in a dual capacity: as circuit for channeling experience gained from enforcement and compliance and as learning fora. Both are anchored in broader developments described below.

Within these parameters, I will start with a discussion of globalization, highlight the key policy issues involved and outline the participants in global activities in section I. Next, I will sketch the legal and regulatory framework of EU regulatory policy in the field of medical devices

⁴ Except for a description of the domestic regulatory structure in Germany (Altenstetter, 1998), subnational implementation networks cannot be included.

and draw out the broader implications of EU policy for four groups of actors. In section III I will discuss the domestic restructuring of regulatory processes and highlight a few problems involved in implementation in national settings.

I. Globalization and Policy Issues: Universal Safety and Quality Standards

Globalization⁵ and regional integration have launched economic, social and political processes, with ramifications into almost every aspect of managing the affairs of public and private interests. The implications of globalization, the liberalization of markets, and regionalization for governance in general and governance in the medical goods sector in particular are not yet clear nor fully understood.

The core efforts at regulatory integration/harmonization in the medical device sector, as in the other key healthcare industries such as the pharmaceutical and the bio-technology industries, is gaining access to markets on all continents under one single regulatory system for medical devices. Ideally, such a ‘single window’ regulatory approach (Peterson and Dery, 2000:89-90) should be based on universal standards and norms for patient care in order to secure safety, quality and performance of medical products through the entire life-time of a medical product, regardless of the location of patients. In practice, such norms and standards are not always achieved for reasons addressed elsewhere.

A few theoretical and practical issues raised by regulatory globalization and regionalization can be offered. Do recent developments suggest regulatory convergence worldwide? Are the goals of policy networks converging or diverging? Who are the major participants? How do policy networks at distinct levels differ from one another within one and the same sector? How are they alike at each level? What explains the differences and the similarities between these networks? What is the policy relevance of these differences or similarities for regulatory policy? Can domestic models of governance (Peters and Pierre, 2000) help us anticipate the attributes of these policy networks, their membership, roles and responsibilities as well as their accountability? Given what we know about domestic policy networks (Richardson 1982), can we anticipate the decision-making styles of policy networks operating at multiple levels?⁶ Is one European regulatory prototype indeed emerging, and if it is, what is the basic

⁵ The concept globalization is used commonsensically rather than being driven by a particular theory. Keohane (2001:1) provides such definition when he writes: “globalization means the shrinkage of distance on a world scale through the emergence and thickening of networks of connections—environmental and social as well as economic.” He insists that the phenomenon is not new and that “globalization depends on effective governance, now as in the past.”

⁶ Although the concept policy style is difficult to operationalize precisely, comparativists agree that countries have developed distinct styles of debating and/or adopting and enforcing policy and that prior policy-making styles and “regulatory cultures” further reinforce whatever

structure and configuration? I will not be able to answer these questions in this paper. Rather, I will now turn to the empirical side of the research.

1. Global Goals, Choice of Rules and Instruments, and Values

Three things are important, if the full background of global regulatory harmonization is to be understood. First, the reason why medical goods are on the global agenda are growing needs for medical goods everywhere. Trade in this area can be expected to grow further. In the past, demographic developments, technological innovations and increasing needs for medical devices in patient care have made the medical device industry a growth industry everywhere. The industry includes world leaders (e.g., Baxter and Becton-Dickinson) who dominate the diagnostic products markets, Siemens, Hewlett-Packard, Toshiba, Philips and GE-Thompson who dominate the world market in electrical-medical equipment, and about three companies which dominate the implantable sector with Boston Scientific being a major supplier of implantables in human bodies worldwide.

Second, in response to globalization, the United States, Canada, Japan and the European Union, and later Australia and Mexico, as well as representatives of national regulatory authorities and American, Japanese and European multinational companies have worked together through a so-called Global Harmonization Task Force (GHTF) to achieve global medical device harmonization by reducing differences between regulatory systems.

The impetus is reported to have come first from two U.S. trade associations, the Health Industry Manufacturers Association (HIMA) and the National Electrical Manufacturers Association (NEMA) which began to bring together specialists from around the world in the late 1980s and early 1990. The formal request for the formation of the GHTF came from the FDA (Higson 1997). The director of the CDRH, Kim Benson, then director of CDRH is reported as having approached John Mogg of the European Commission and suggested that "since the FDA was committed to revising its GMP regulation in the direction of ISO 9001, a collaboration effort could harmonize what the FDA was going to do with the resources being used in Europe—

- ISO 9001, *Quality systems—models for quality assurance in design, development, production, installation, and servicing*, and
- EN 46001, *Quality systems—medical devices—Particular requirements for the application of ISO 9001*" [italics in original].

The European Commission is reported to have responded favorably to the American invitation. Commission paper was circulated at the Global Medical Device conference in Nice, France in September 1992. The decision to engage in a joint effort of regulators and industry was taken then (Higson 1997).

At present, the universe for medical devices in the world's countries falls primarily into

domestic policy-making style has been prevalent (Vogel, 1986; Scharpf 1992).

two groups: (i) countries with regulatory systems, although they may substantially differ from each other and (ii) countries without regulatory systems or developing them. The first group of countries includes the US, EU, Japan, Australia, New Zealand, Canada, Mexico and EFTA. Countries without regulatory systems or developing them now include Latin American and Central and Eastern European countries.

The GHTF is composed of a small circle of key players nominated by multinational companies, high-level government officials as well as professional specialists reflecting a geographic pattern with separate representation from Europe, the USA, Canada, Australia, New Zealand and Japan. Usually, the international standardization organizations such as CEN, CENELEC and ISO also attend these meetings. Clinical and other innovators at the cutting edge of medical innovations participate in the respective committees and subcommittees working out the standards for medical device manufacturers.

The pattern of representation differs across the three trading blocks. For Europe, the GHTF is composed of Commission representatives (DG III) and representatives of the industry appointed by the respective European trade associations. The total number of European attendees has oscillated between a total of six to eight individuals. The North-American continent has been represented by four government officials, typically one official from Canada, one from the Center for Devices and Radiological Health of the FDA and two industry representatives. Asia/Australasia has sent between three to four representatives, one from the Australian Therapeutic Goods Administration and two officials each from the MHW Ministry of Health and Welfare and the industry in Japan. This pattern has been fairly stable since 1992. And, depending on the particular decision-making levels, additional participants are part of policy networks. Whatever bargains are struck and agreements reached largely go unnoticed by the public, the media and the social sciences but watched closely by regulatory affairs specialists and legal advisers in each country.

Global and regional rules have been set slowly. As experience with the enforcement of the first two directives⁷ is being gained, revisions of two directives and informal rules (e.g., the many Commission-supported guidelines, so-called MEDDEVs) are being made to enhance effectiveness and legitimacy (Scharpf 2000). Hence, revisions of “goals, rules and instruments as well as values” are appropriate, though crude, descriptions of the activities of policy networks in the medical device sector.⁸

⁷ The AIMDD became effective in the member states in 1993, the MDD in 1995 and the IVDD in 2000.

⁸ EU rules include all Treaty-based rules, primary and secondary legislation, standard operating procedures and judge-made rules of the European Court of Justice. Routines and practices have evolved around them. International rules governing international trade are set through the WTO and other international fora. However, when compared to the national and European rules, international rules tend to be set in vague and general terms and complemented

In the words of the *Global Harmonization Task Force*:⁹

“Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that manufacturers of medical devices follow specified procedures during design, manufacture and during marketing. The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable. This is achieved by identifying and developing areas of international co-operation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices.”

Since its creation, the GHTF has worked through four Study Groups (SGs), with SG1 primarily dealing with responsibilities in the pre-market phase and SGs 2, 3 and 4 primarily with after sales responsibilities. This demarcation is rather crude. Figures 1 and 2 outline the regulatory tasks for each SG. Each task can be considered a “veto-point” because consensus among the experts is required.

Figures 1 and 2 about here

SGs are composed of the same group of participants, respecting both a geographical balance and balance between government regulators and industry representation. For the European continent, apparently, representatives of the UK Medical Device Agency (MDA) have been allowed to act in the name of the Twelve, later the Fifteen. They are listed most frequently as chair of working committees.¹⁰

Study Group 1 (SG 1) was charged to identify aspects of regulatory systems in use in the major trading regions, identify features of these systems which have a common basis but different application and those which may present obstacles to uniform regulations, and come up with concrete proposals for harmonization activities.

Study Group 2 (SG 2) was asked to inventory areas in which measures were necessary to

by more specific rules governing a sector. The medical device sector is a highly segmented sector. For this reason, sectoral rules and procedures are emerging slowly.

⁹ For this section information was pieced together from GHTF documents, grey literature, and conference proceedings. Interviews were also conducted with Commission officials and a few representatives from European industry.

¹⁰I have not yet looked at the field information on the composition of the SGs in any systematic fashion over time.

assure post-market monitoring of the appropriate use and performance of medical devices. This meant inventorying the need for post-market surveillance, developing procedures for reporting incidents with devices in use and appraising the level of understanding of the importance of reporting incidents with devices for consumers and users.

Study Group 3 (SG 3) was directed to look into the issue of good manufacturing practices and guidelines for specific parts of quality system application. And, finally,

Study Group 4 (SG 4) was requested to prepare guidelines for a common approach to auditing a manufacturer's existing procedures for appropriate application of quality systems in manufacturing.

Each SG has issued consensus-based documents in its field of expertise. Some have been accepted as GHTF documents, others advanced to GHTF proposed document status. Others are working drafts. Progress in producing these documents in individual SGs has varied. In some instances, conflicts and disagreements occasionally have been severe. In fact, the work of one SG sub-committee suffered from unsurmountable controversy leading to a complete breakdown of communication among North American and European participants in the year 2000.¹¹

Table 1 on the Global Harmonization Task Force and Participants summarizes the current leadership, area of expertise and work plan for each SG. The European Commission was chairing the GHTF between 1992 and 1998 when the FDA assumed the leadership of the GHTF.

Table 1 Global Harmonization Task Force: Participants: Australia, Canada, Europe, Japan, Mexico, USA

| SG 1 | SG 2 | SG 3 | SG4 |
|---|---|--|---|
| Regulatory Systems | Post-market Surveillance | Quality Systems | Quality Systems Auditing |
| Convenors: Maurice Freeman (Quintiles-MTC) | Larry Kessler (FDA-CDRH) | Kim Trautman (FDA-CDRH) | Convenor: Robert Allen (UK-MDA) |
| Comments on: * EU Directive on IVD * Draft Canadian Medical Device Regulation | Work on harmonization of requirements for reporting of adverse events; Device nomenclature; Requirements for Exchange of regulatory | Comments on: * Japanese GMP * FDA GMP Regulation | Guidance on the auditing of quality systems for the design of medical devices |

¹¹For a complete update of the status of the documents issued by the GHTF and its four SGs, see The Regulatory Affairs Journal (Devices). February 2000, pp.58-59.

data

| | | |
|---|--|-------------------------------|
| <p>Work on harmonization of technical documentation Essential Principals-Declaration Reference to standards-Declaration</p> | <p>Issue of guidance on implementation of quality systems. Work on guidance on design control; Process validation.</p> | <p>Auditor qualifications</p> |
|---|--|-------------------------------|

Source: HGTF.SG1.NO31RI. Draft of 15 October 1999 (Permission to publish required (?)).

The third (3) policy instrument for global and regional regulatory integration are *bi-lateral mutual recognition agreements* (MRAs). Activities surrounding MRAs are intentionally kept separate from the activities of the GHTF. By now, several MRAs between the European Union and other international actors have been signed. Each MRA, negotiated separately, differs from the others in substance and rules. However, except for the regulatory regime in the US and Japan, the regulatory regimes of the remaining countries participating in global harmonization efforts are closer to the EU approach than they are to the FDA approach.

Why Mutual Recognition Agreements (MRAs), one may ask? The move by governments of advanced industrial societies to enter into MRAs with the European Union should not come as a surprise. The spatial reach of EU regulatory requirements is extraordinary. It is one reason why it has been so important to American industry, the most important exporting supplier to the EU. The reach goes far beyond the single market of the fifteen and includes all EFTA countries and the five candidate countries in Central Europe in the first round. Probably after 2005, the EU regime will extend to another five Eastern European countries.

The US-EU MRA. In 1997, cooperative efforts among North American and European Union representatives and participants from the relevant industries culminated on June 5, 1997, in the signing of a draft *Agreement on Mutual Recognition (U.S/EC Final Draft)* between the United States and the European Union, with a Sectoral Annex on Medical Devices. This MRA outlines the rights and obligations of the partners to the agreement and confidence building activities between the U.S. and the EU. In the preamble the MRA states that it “will further public health protection, will be an important means of facilitating commerce in medical devices, and will lead to reduced costs for regulators and manufacturers of both Parties” (Preamble).

In theory, this agreement and in particular the intended joint development of a notification and alert system for the recall of products as well as product quality has implications for the safety and well-being of people of all ages on all continents. In practice, the implementation of this MRA has been delayed because of controversies, disagreements and limited resources. So-called confidence-building exercises between the FDA and the EU have started slowly, with each side putting the blame for the delay on the other side. So-called Conformity Assessment Bodies

(CABs) to assess compliance with the regulatory system in the partner's country have only been appointed in 2000.

From the beginning, the FDA has had strong reservations in regard to the EU regulatory approach. One key FDA criticism has referred to the organization of oversight functions by national regulators over regional and grass-roots implementing agents (or certification bodies) and the organization of other *operational responsibilities* in the domestic implementation process. In addition, criticism has arisen from within the European Union, governments and regulators and notably a few leading countries in this sector such as Britain and France. As the EU's largest exporter of medical products, Germany has held out the longest and resisting any changes in the existing EU directives. Since early this year, Germany finally has joined France and the UK in their support of a revision of the three directives.

A few third party bodies have traditionally served as intermediaries between national regulators and manufacturers. Depending on the country, some are public, others quasi-public, and still others private organizations. In the past, they have served as building blocks (the "macro-structure") for enforcing regulatory policy specific to medical devices in each country, and they continue to play an important role under EU regulation. These certification bodies embedded as they are in a country-specific institutional context, however, have operated in different ways.

The last two years of activities and meetings among the relevant actor groups at both EU and national levels have been fully devoted to the improvement of the operation of third-party certification bodies. Yet, even with the EU regulatory regime in place, no regulator anywhere comes close to the power of the FDA over the pre-market application process. We know much less about monitoring post-market surveillance of the market and following up on reported accidents or incidents with medical products.

If there is one observation emerging from this research, it is that the signing of negotiated, bi-lateral mutual recognition agreements between the U.S.A. and the European Union and between the European Union and Canada, New Zealand, Australia and now Japan masks substantial differences in the existing regulatory regimes. Table 2 provides a broad profile of similarities and differences between countries. Regulatory convergence has occurred while leaving in place substantial differences.

Table 2: Comparison of pre-market requirements between GHTF members

| Pre-market Requirement or Related Aspect | Similarities Between Countries | Differences Between Countries |
|---|--------------------------------|----------------------------------|
|---|--------------------------------|----------------------------------|

| | | |
|--------------------------------|---|---|
| Classification | Devices are categorised based on risk | * The number of categories * The risk category assigned for a device |
| Use of Standards | Technical standards are utilised | * Different technical standards may be used * The amount of data or information submitted documenting conformity |
| Quality Systems Requirements | Records are created and maintained | Type and amount of data and information required or recommended |
| Technical Data and Information | Data and information are maintained and available to regulatory authorities or conformity assessment bodies | Format and content of data |
| Premarket Evaluation | Degree of evaluation based on risk category of device | Who evaluates the data, the intensity of evaluation, and the length of the review process |

Source: GHTF (?).

3. A European regulatory agency? Commission DG III, representatives of European trade associations and European industry as well as domestic regulators from a few countries have acknowledged the validity of some aspects inherent in the criticism by the FDA. Yet, they are unlikely to follow the position of the FDA. The FDA model, taken to its logical conclusion, means the creation of a European Agency for Medical Devices similar to the European Agency for the Evaluation of Medicinal Products (Majone 1997). A “high level” political demand from France was briefly on the European agenda in 1997/98, then disappeared for a few years only to reemerge again as a future option to be debated and decided upon when the review of the EU pharmaceutical regime is completed, probably in 2003.

European governments have not embraced the idea of a European-wide agency any more than European industry. The two U.S. trade associations (HIMA and NEMA), the Transatlantic Business Dialogue (TABD) and American subsidiaries in Europe, all are strong advocates of the EU regulatory approach preferring it over the approach taken by the FDA.

The record. Today, there is no single binding global regulatory regime, despite many

international and regional activities going on since 1992. However, most pre-market and after sales responsibilities, notably registration of medical devices, remain with national authorities. Yet working through a Global Harmonization Tasks Force (GHTF) this industry has promoted and partially achieved regulatory convergence between the three leading regulatory regimes of the EU (with 28 per cent of a share in the global market), the USA (48 per cent) and Japan (15 per cent) (HIMA).

An industry insider provides a telling summary of the GHTF and MRAs. “Instead of convergence there is an increase in complexity and a growing divergence. MRAs and global harmonisation are developing into two different concepts. MRAs are not providing equivalent market access, and global harmonisation continues to be a distant vision....It is not the product design and manufacturing processes that need to be harmonised but the excessively bureaucratic and regulatory administrative systems...Excessive regulation will stifle and retard medical development, increase the costs of market entry, discourage investment in the industry, and ultimately deny patients the potential benefit” (Cutler 1999:2-3).

He speaks to the increasing complexity without any “effective control and the “proliferation and veritable confusion of documents from three sources:” (i) the GHTF, (ii) from the developments of MRAs, and (iii) from ISO/TC 210 and other ISO Committees for medical devices.. The GHTF has no official status and hence its output will not be recognised whereas technical standards (eg: from ISO) have a presumptive regulatory role” He points to the “danger of elevating the GHTF into a “super” regulatory authority.”

Table 3 chronicles the major events and activities leading to the institutionalization of a global and regional regulatory regime for medical devices.

Table 3 Time line of institutionalizing a global and regional regulatory system for medical devices

| Year | National Level | EU-level | Global level |
|---------------|---|----------------------------------|---|
| Prior to 1990 | Different national rules & instruments in a few European countries; focus on different priorities | <u>Old approach</u> legislation | ? |
| 1990 | | | |
| 1991 | | Adoption of the AIMDD* | |
| 1992 | | | Creation of the GHTF, Sept. Nice |
| 1993 | The AIMDD comes into effect in member | Adoption of the umbrella medical | GHTF meeting, January Brussels GHTF meeting, November, Tokyo |

| | | | |
|------|---|--|--|
| | states; co-existence of national & EU rules | device directive (MDD) | |
| 1994 | | | GHTF meeting, June, Montreal |
| 1995 | The MDD comes into effect in member states; co-existence of national & EU rules | | GHTF meeting, June, Vancouver |
| 1996 | | | GHTF meeting, October, Lisbon |
| 1997 | | De-coupling of IVD-products from products based on animal or human tissue. | Signing of the US-EU MRA |
| 1998 | | The IVDD is adopted. | US-EU MRA comes into force; significant delays. MRA between the EU and Australia and New Zealand signed; MRA between the EU and Canada signed (?) GHTF meeting, February 1998, Sydney |
| 1999 | | | Clash between US and EU over the the implementation of the US-EU MRA continues; MRA between the EU and Australia and New Zealand re: diagnostic products. |
| 2000 | The IVD comes into effect; co-existence of national & EU rules | | Confidence building measures take off. MRA between the EU and Canada re: diagnostic products; |
| 2001 | | Revision of the AIMD, MDD & IVDD under consideration | Intensifying regulatory cooperation; moving closer; yet co-existence of three regulatory regimes; negotiations with Japan on-going. |

II. EU Regulatory Policy¹²

The regulatory system for medical devices in the European Union is young and twenty-five years behind the regulation of medical devices in the United States. Although three EU directives have been adopted, are European law and binding on national regulators, the sector suffers from a good many uncertainties of how best to proceed to regulate medical goods and equipment for worldwide use.

Medical device regulation in the European Union was the product of a political choice at the *highest politics* level surrounding the adoption of so-called *new approach legislation* in the mid-1980s, which affected 17 industrial sectors such as telecommunications, product safety, construction products and medical devices among others. It was a “history-making” decision of the Council and the Commission to end *old approach* legislation, which wrote specific standards into legislation, and adopt so-called *new approach* legislation. France, Germany and the United Kingdom and the remaining EU members accepted the entire legislative package in order to set in motion the single market, which was in the national interest of the three European leaders and their industries. But they have widely differed about the application of six principles.¹

Once the entire legislative package was enacted, conflict resolution on technical, substantive and scientific issues in each policy sector shifted from the “high politics” level to highly specialized and technocratic, formal and informal committees, working groups and issue networks. Representatives of the respective ministries and the ministries of economics, advisors and scientific experts and experts from relevant multinational companies have dominated the decision-making process. The medical device sector tracks this shift from the “high politics” level of decision-making by the Council to technocratic policy-making by expert groups each operating under the leadership of the Commission and occurring in all policy sectors (Peterson and Bomberg, 1999).

Figure 3 provides a profile of the EU regulatory structure of regulatory decision-making by the so-called Art. 7 committee composed of DG III officials and national regulators. The next level down is the Medical Devices Expert Group composed of representatives from DG III, third party certification bodies (Notified Bodies (NBs) and the Industry. The Working Groups are composed of Commission-led DG III, national regulators (CAs), third party Notification Bodies (Nbs) and a variety of industry experts. Figure 3 about here

These are the members of policy communities which have produced the rules for the new EU regulatory regime. They have the knowledge and information and are the insiders to the negotiations in Brussels. Depending on the country, we are dealing with a handful of officials, scientists and company experts.

1. What are not medical devices in European law?

¹²For a more detailed account, see Altenstetter 1994; 1996;1997; 1998. 2001a 2001b.

According to European law, a medical device is not an organ, not a prescription drug, not a transplant nor a blood product or a cosmetic product. These products are subject to different regulatory mechanisms which vary in regulatory requirements, underlying philosophy, and tools to achieve objectives. For example, under so-called *old legislation* a regulatory regime for pharmaceutical products has been evolving over a thirty year period. A set of strict rules and procedures is well established, and a European Agency for the Evaluation of Medicines is in place. Yet the shadow of the pharmaceutical regime remains long affecting many activities in the medical devices area.

Three EU directives specific to medical devices roughly correspond to four distinct producer sub-sectors: (i) the medical-electrical sector, (ii) the non-electrical product sector, (iii) the sector of implantables and (iv) diagnostic products. Within each group of products, the term medical device is used for a range of widely differing products: active implantable medical devices such as heart valves or hip replacements, medical-surgical goods and heavy equipment, and in-vitro diagnostic products for laboratory medical analyses.

New approach legislation is based on six principles.¹³ First, CE-marking¹⁴ serves as a guarantee of conformity to particular regulations and should not be confused with the term European Community.² In the industry's view, "the quality-based regulatory approach ensures that quality is built into products right at the beginning of the manufacturing process" (??). It is a kind of market authorization but should not be confused with pre market approval/licensing of individual products and a strict product testing regime which is operation in the pharmaceutical sector.

Second, directives in their entirety need to be transposed into national law. They specify the essential requirements (technical-scientific and clinical) in highly detailed annexes which must be met as a precondition to obtain market authorization. Under normal circumstances, a social scientist would bother little to find out about legislative annexes. However, in this case, it is a must. The annexes stipulate the substantive elements of EU policy on quality, safety and performance for each group of medical devices and give meaning to these three concepts. Ideas

¹³ In *old approach* EU legislation technical standards and technical specifications were written into directives. *New approach* legislation refers to performance requirements and encourages the use of standards to deal with the essential requirements. However, after ten years of EU regulation in this field, at the demand of France and a few other coalition partners considerations of technical specifications are back in the debates on in-vitro diagnostic products and high risk products using cells, tissues or bones, and requirements for clinical investigations. The results are conflicting views among the leading participants concerning appropriate technical specifications, as they existed under the *old approach* legislation and delayed much standardization-work.

¹⁴ Contrary to a widespread perception, it does not stand for *Communauté Européenne*. Rather, it means *Conformité Européenne*.

about them have been the target of conflicts and disagreements among French, German and British experts and policy-makers ever since the debates about medical devices regulation started in the late 1980s.

Third, the annexes make references to harmonized EN or ISO standards (rather than national standards). Studies on standard-setting work (Schmidt and Werle 1993) have shown that standards work provides opportunities to write one's own ideas about quality, safety and performance into the standards. In consequence, standard-related work tends to be dominated by experts from the relevant industrial sectors, the micro-engineering and medical-scientific professions as well as national standards offices in each country (DIN in Germany, BSI in Britain and AFNOR in France).

Fourth, member states can invoke the safeguard clause (article 36 of the Treaty of Rome) in the interest of public health when they have reasonable doubt that essential requirements for products are not respected or when there is evidence that product standards are applied inappropriately or do not exist. Member states can act within a parameter set by the Commission. This is the case when a) a risk is proportional with the perceived risks, b) is product specific, and c) temporary only. So far, France has taken action regarding condoms, breast implants and animal tissues and has an open query about electrical safety. And the UK has taken action in regard to class III implants.

The European Court of Justice has not yet provided a clear-cut ruling on the conditions under which member-states can invoke this clause. One source close to the French regulators said: "France has never won a case." The whole notion of a precautionary principle is entangled with political and legal issues, with political considerations sometimes stronger than legal considerations. Unsurprisingly, the ECJ puts a high premium on legal considerations.

Fifth, like other regulatory systems in this field, the EU system is based on a four-fold classification system of medical goods by risks. The higher the risk potential the higher the regulatory requirements.

Finally, home country control governs implementation, and member states have considerable discretion in organizing the implementation of each directive.

These ground rules are universal in Europe and are not tailored-made to each category of products as under the *old approach*. However, to allow for the unique characteristics of medical devices exceptions from this five-step legislative format were made and extra and largely medicalized articles were added to the latest medical device-specific regulation.

2. Legal and regulatory framework for medical devices

The Active Implantable Medical Device Directive (90/385/EEC), the Medical Devices Directive (93/42/EEC) and the In-Vitro Diagnostic Directive (98/79/EC), which amended important

provisions of the previous directives, call for three regulatory requirements. Compared to what existed before, they can be considered a real innovation. First, they introduced new procedures for market authorization across Europe, with the CE mark providing a passport to regional trade. Second, they focused on post-market surveillance (PMS) and the monitoring of after sales responsibilities. Finally, from the perspective of health safety and patient protection more importantly, they intend to strengthen medical vigilance and the reporting of adverse incidents encountered in the delivery of health services in doctors' offices, health sites and at home. The directives have come into effect in the member states in 1993, 1995 and 1998, respectively, while the transition period for IVDD products will last until 2003 and 2005.

The EU directives define a medical device as: "Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" (MDD).

In-vitro diagnostic devices are a subgroup of medical devices and include reagents, kits, instruments, and equipment for medical laboratories. As laboratory testing products, they are vital to prevent, diagnose, treat and monitor disease. The directive also covers devices for self-testing by patients and control materials as well as calibrators intended for use in combination with the reagents and equipment mentioned above. The directive excludes reagents produced primarily by hospital laboratories for their own use.

3. Regulatory implications for public managers, regulators and bureaucrats

The regulatory agency or ministry serving as competent authority has three roles: as rule-maker and direct participant in European-level policy processes, as rule-maker for implementing decrees, guidelines and other provisions and, finally, as overseer of domestic implementation. In practice, the situation is more complex. Current policy makers and public managers have inherited from their predecessors negotiated understandings, laws and administrative routines, which can severely restrain the implementation of new regulatory efforts. Of the three roles for public managers, the overseer role is reported to be the most in need of change. The implementation of EU directives requires leadership in public management, influence and persuasion. In reality, command and control strategies are imposed on front-line implementers through a series of never ending implementing decrees or ordinances. In a few rare cases such as in France new resources are not made available for new tasks.

Most countries needed to put in place new procedures and rules from scratch. In France, Germany and the United Kingdom, implementation of EU directives has meant the restructuring

of elements of prior practices by national regulators, the industry, certification organizations (NBs) and users. Yet implementation activities clearly show that old ways of thinking and acting are resurfacing, and in some countries more than in others. Indeed, implementation is a reality check for France, Germany and the United Kingdom. They see themselves as having provided leadership in setting up the regulatory regime in the European Union. Yet leadership required for implementation is not identical with leadership required for policy adoption and reformulation.

4. Regulatory implications for the industry

The challenges and opportunities facing a highly knowledge-based industry are multiple. As with the bio-industry, there is no medical device industry *per se*. Instead, there is a cluster of producer sectors that manufacture goods using technologies from practically all industrial sectors.

A most important challenge is to come to terms with the new regulatory requirements in the medical device sector which the industry and distinct producer groups did not face before. This sector has a few global companies while the bulk of the producers are small and medium-sized enterprises. Most observers agree that the opportunities outweigh the inconveniences by far. European directives provide:

- one market authorization for the free movement of medical devices on an integrated market within the European Economic Area and soon including countries of Eastern and Central Europe;
- access to an integrated European market representing about 28 percent of the world market and eventually access to a global market with three regulatory regimes co-existing.
- competition based on the CE mark. This means that all European manufacturers—large and medium and small (PME)—are subject to a quality assurance system for manufacturing.
- mutual recognition of licensing and certification of conformity assessment with essential requirements by notified bodies (NBs).
- reference to and application of European standards (about 100 ENs are relevant to medical devices). Recent standardization mandates by the Commission to CEN and CENELEC have focused on risk assessment and management; ways to avoid or reduce the possibility of user errors, and the improvement of the decision-making process about what constitute acceptable risks and benefits.
- legally binding annexes meticulously detail the essential requirements and quality instruments, including classification of medical devices according to risk levels and four product classes (class I, class IIa and IIb, class III). The higher the risk level the higher the regulatory requirements.

Finally, the CE mark requires clinical evidence to prove performance but does not require evidence to prove efficacy and effectiveness, unlike pharmaceutical drugs and the FDA's regulatory regime. However, unlike consumer goods which must be safe but do not need to work, the performance of medical devices is a legal requirement for all medical goods. Performance is determined by the manufacturer and certified by notified bodies (Hodges, 1999).

For cultural-political reasons, the notion of manufacturers' self-certification is unacceptable to any government of the right or the left in France. In consequence, national procedures, including those for clinical investigations vary greatly in the three countries (Sorrel, 2000).

The incorporation of clinical investigations into the essential requirements means: the utilization of medical devices must not compromise the clinical state of a patient; the medical devices must achieve the performances as indicated and declared by the manufacturer; secondary and undesirable effects must constitute an acceptable risk based on the state of knowledge. Risk analysis is to identify and anticipate risks associated with the utilization of medical devices, and to estimate likely risks. Whatever method is used to obtain the CE-mark, the manufacturer is responsible for risk analysis and to document it.

5. Regulatory implications for users and patients:

The three Eu directives on vigilance and medical vigilance are innovating in that they do address the concerns of patients and users. However, the approach has not been without its critics. The important issue is how and whether national decision makers for medical vigilance can create sufficient incentives for local implementers to follow through with centrally imposed command and control strategies and whether those who are responsible for the enforcement of medical vigilance at the local level follow the national instructions, guidance and recommendations. According to European law, incidents are to be reported within ten days and near incidents within 30 days.

Depending on the country, national regulators define vigilance broadly and others narrowly. Some have created a fairly streamlined organization to inquire into the type and cause of incidents once incidents are reported to a central authority, the so-called Competent Authority (CA) in EU legalese. This authority decides on the nature and seriousness of the incidents and the corrective measures to be taken. Elsewhere, the central authority has taken a minimalist approach oriented solely at the control of products while delegating health-related issues to the appropriate health authority(ies).

The scope of medical vigilance, as accepted at the European level, is broad and concerns all who work in the health care system.

An adverse incident is defined as an event which gives rise to, or has the potential to produce, unexpected or unwarranted effects involving the safety of patients, users or other persons. Averse incidents in medical devices may arise due to shortcomings in:

- the device itself
- instructions for use
- servicing and maintenance
- locally initiated modifications or adjustments
- user practices, including training
- management procedures
- the environment in which it is used or stored
- incorrect prescription

Conditions of use may also give rise to adverse incidents, e.g. environmental conditions (electromagnetic interference); location (e.g. devices designed for hospitals may not be suitable for use in the Community or ambulances)[2].

In theory, the establishment of a medical alert system is laudable. In reality, the differences in post-market surveillance and medical vigilance in domestic settings are significant. To achieve these objectives requires moving away from handling the notifications of adverse incidents as bureaucratic requirements toward a broader view endorsing the importance of medical vigilance in the interest of public health for everybody. A final outcome of EU-level activities may be the establishment of a genuine observatory of health risks--perceived and actual in Europe. However, both are a long way off from becoming a reality.

III Restructuring domestic regulatory processes: decentralized enforcement

The link between EU directives and national implementation networks need further explanation. From past research on implementation/enforcement, we know that the greater the number of levels of analysis--macro, meso or micro--the more complex, dispersed and differentiated the actual scenarios of networks and institutional settings become, and the more difficult it will be to assign good performance or good enforcement to a policy in question, the politics of networks, or to the broader political environment in which networks operate.

In this context, three kinds of rhetoric about the enforcement of EU directives in the member states as well as the issue of accountability of subnational and local implementing agents to national decision-makers are particularly confusing. The same is true for the liability of member states for failing to implement EU law to the European Union. The reason why this rhetoric is confusing is that it conveys one image of reality when in fact reality varies considerably.

In theory, lines of accountability are vertical. However, lines of accountability are more tenuous. Sometimes they are not linked and in the worst case scenario are non-existent. Government is divided into two or three levels of government at which we usually think of policy being formulated and rules for enforcement and compliance being written and applied, that is, the national, regional and local level. This is natural since it is at these levels, depending on the country, that political power is exercised, decisions on policy and regulations made, and people participate in the political process through their vote.

1. Accountability and medical vigilance. Even if we take a comparatively simple illustration of a regulatory policy on, for example, medical vigilance,--which globally is largely run by government experts and networks of scientists, clinicians and innovators--its domestic implementation requires activity at all levels. Responsibilities for operations are dispersed through numerous authorities and agencies, and advisory bodies at the macro-level. At the meso-level responsibility for decision-making on implementation is dispersed between a hierarchy of administrative committees reporting to hospital management and a hierarchy of health care providers, specialist committees, clinicians and an array of different support staff. At the micro-level, a set of clinical decision-makers and nursing staff are the likely players.

In this example, consensus on policy objectives at the national level would be relatively

easy to achieve if we were to assume that a coalition of purchasers, payers and government supporters back the policy on medical vigilance. Such a policy would include, among others, measures for reporting incidents and accidents, evaluation of technologies, changes in hospital accounting, controlling professionals' behavior through licensing and accreditation, requiring continuing education and training, measures for the control and maintenance of capital investment, etc. However, such assumptions cannot be made. Even reporting and evaluation, just to pick only two examples, are frequently not the responsibility of one body, reporting being the responsibility of hospital management and the evaluation of incidents, for example, being in the hands of clinical committees, multiple local and national evaluators, some governmental and many private. Control over professionals is typically enforced through different channels and authorities.

If the national level does not provide the necessary resources (e.g. funds and information to mention only two) for the implementation of a policy on medical vigilance, these activities will be in competition with patient care, research and others tasks carried out inside hospitals. Similarly, limited local staff will have to be reassigned from traditional duties to new duties. Given the constraints of hospital budgets and the shortage of manpower in many countries, staff is asked to take on more responsibilities. The results are slippages which should be expected as a matter of course rather than as an exception.

The same applies to the enforcement of compliance with regulations concerning the maintenance, servicing and the procurement of equipment and therapeutic products. This requires the cooperation of hospitals and private suppliers of medical systems. Yet, in all these areas we know very little. In particular in all three countries a new partnerships between hospitals and supplier companies are propagated by the respective governments in power. Given that we know next to nothing about existing relations between hospitals and suppliers in the past, it is even more difficult to figure out how this new partnership will play itself out in the future.

Local reporting of accidents and incidents will rarely be uniform and reliable throughout any country. Geographic differences in the frequency and intensity of reporting on adverse incidents in, for example, France and the United Kingdom, was striking but really not surprising, given the cultural and geo-political differences in regions of France and the United Kingdom. Yet reporting is a precondition for taking any reactive measures at the national level.

In clinical settings, a hierarchy of hospital committees co-exist inside hospitals. Some committees primarily have support functions and others primarily clinical functions. The management of hospitals has been appropriately described as *hospital management by committees*. This seems an appropriate categorization which is little understood. Information that circulates inside each hierarchy flows to the top first before it can be used. By the time it can be used, it may be outdated. In most cases, the circulation of information does not run through the system, contrary to the expectations of top level managers and policymakers. Special efforts are seldom made to keep the information flow going.

2. Evaluating evidence. The number of stakeholders who participate in meetings when the evidence of evaluation and appraisal processes is judged varies greatly among the three countries. For example, NICE is proud to have an interdisciplinary mix of participants. NICE's Appraisal Committee includes a huge cross-section of disciplinary specialities.¹⁵

The statutes in all three countries recognize a select group of stakeholders as legitimate, despite the rhetoric of "open government" everywhere. The composition of committees sometimes mirrors the demands for political legitimacy of any decision-making process and the need for specialized expertise, regardless of where policy is being implemented. Yet, a "politically correct" composition of committees does not secure that the arguments put forward by the participants on behalf of the group they represent are heard and acted upon. For example, arguments put forward in favor of patients and/or particular treatment options tend to be subordinated to cost concerns. In fact, the regulatory process in the three countries makes no allowance for hearing patient advocates nor inviting a wide cross-section of healthcare professionals to participate in regulatory processes.

From a policy perspective, it may seem strategically wise not to involve all the agents referred to above in the formulation of a national policy on medical vigilance, if rapid approval is desired. The pitfall of such strategy, however, is that their full cooperation is absolutely essential for implementation of the policy. If regional and local authorities and administrative offices are not made aware from the beginning of the importance of their particular activities for the achievement of this overall national goal, they will be less likely to make a special effort, and may be apathetic to the whole implementation process.

Textbooks on regulation say that regulations must be perceived to be legitimate and effective at all levels, if they are to work. This applies to policymakers: politicians, medical societies, healthcare professionals, clinical specialists, purchasing departments, overseeing committees, etc. regardless of the level where they operate, and regardless of whether they perform support or clinical functions, work at the bed-site, a hospital laboratory or a ward. Considerable guidance, training and the creation of awareness among the field staff is required.

National regulators often are not aware of any bottlenecks. Field experience seldom is fed back when existing policy is revised. To use one illustration from the field work. Most decision-makers in central offices and top hospital managers assumed that the vigilance system required under new European law will be implemented by all staff members who can be held accountable by those on the top. Of course, they are accountable. They are liable under hospital and employment laws, professional codes and professional liability rules. Yet formal accountability

¹⁵ NICE Appraisal Committee's composition consists of 2 hospital physicians, 1 pharmaceutical physician, 1 surgeon, 1 pathologist, 2 general practitioners, 1 public health physician, 1 hospital nurse, 1 community nurse, 1 clinical pharmacologist, 3 health economists, 1 pharmacists, 1 bio-statistician, 2 patient advocates 3 health managers.

mechanisms are no guarantee that a vigilance system will perform well in the interests of patients.

3. Restructuring government functions and decision-making bodies. EU directives have had other unexpected side-effects. All three countries have engaged in restructuring government functions. In the three countries included in the study, a national agency rather than the ministry of health has served as regulator: the Medical Device Agency (MDA) in the UK, the Health Care Product Safety Agency (AFSSAPS) in France, and the BifArM in Germany. In-house staff and experts under contract to the agencies jointly review and evaluate manufacturers' submissions for product approval, including documentation on clinical trials, performance, efficacy, etc.

The United Kingdom launched a few new initiatives (e.g. horizon scanning). Rather than delegating it to the National Institute of Clinical Excellence (NICE)-already involved in healthcare technology assessment--it delegated out this task to a center of excellence located at the University of Birmingham, thus generating more diffused new institutional arrangements for the regulatory circuit.

France and Germany (with an insurance-based health care system) have used a two-pronged evaluation approach following closely the prototypical evaluation process for pharmaceuticals. Decisions on market approval will be made by separate decision-making committees. For example, in France a manufacture must submit documentation and clinical evidence to AFSSAPS for market approval. Evidence will need to be submitted to the *Commission de l'Evaluation des Dispositifs Médicaux* (CEDM) which will evaluate the benefit of a new product. A second committee attached to the ministry of health, the *Comité Economique des Produits de Santé* (CEPS), a pricing committee, will fix the final prices for medical devices and for pharmaceuticals. To allow for the most efficacious and cost-effective treatment CEPS is intended to have more budgetary flexibility References

In the past ten years, France and the United Kingdom have organized the identification and appraisal of emerging and established technologies prior to their launch into the system. This pre-market phase primarily involves manufacturers of therapeutic products and equipment, representatives from their respective trade associations, government offices and clinical specialists serving on advisory committees under the leadership of the ministry of health.

The identification of candidates for reappraisal because of clinical ineffectiveness, steep costs, or both when compared to other products and techniques, happens after the products are in use. In this post-market phase, a different set of stakeholders is involved who have varying after-sales responsibilities and who are accountable to the top the top being the MDA (UK), AFSSAPS (France) while regulatory responsibilities in Germany are shared between federal and regional regulators.

Information in these processes runs up and down the system in each country and is largely reserved for a very small group of decision-makers: government experts, clinical experts and

industry representatives. Despite the rhetoric of “open” and transparent government, most decision-making processes on coverage, reimbursement, pricing, reporting and evaluating incidents and accidents as well as hospital procurement suffer from transparency and lack of openness. Even expert recommendations for remedial policy measures are reported to be ignored by the respective agency. Contrary to the claim of agency independence which interviewees insisted upon, realistically, they cannot isolate themselves from political pressures and the broader political environment.

Participants privy to the negotiations over these issues seem to have internalized the notion that at the end of the day decisions must be justifiable on the grounds of value for money. Even demands for assessments—in the interest of making better treatment options available to specific population groups—are subordinated to concerns for cost containment. Under these circumstances, the beneficial effects of healthcare technology assessment can easily revert back to being harmful when decisions are made to exclude treatment options from the reimbursement list. There is evidence to document this.

Major decision-makers on the inclusion or exclusion of procedures with medical devices include representatives from the treasury, the ministry of health, possibly the ministry of economics, regulatory agencies for medicinal products and medical devices and representatives from the national payers (NHS or NHI). Health economists as advisors are present everywhere. National legislators mandated economic analysis. However, economists fail to draw a distinction between drugs and medical devices and apply an evaluation methodology that has worked for the evaluation of prescription drugs to medical devices faith in scientific economic analysis diminishes or vanishes entirely.

If medical techniques are found to be ineffective, there is a need to change clinical and other routines in hospitals. At this appraisal stage, the decision-making process in France, for example, has tended to be dominated by the top level of a hierarchy of hospital management committees and by the top level of a hierarchy of specialist committees and other healthcare providers, nurses, staff, etc.. Clinical committees judge clinical effectiveness. Joint hospital committees assess whether or not incidents with drugs, medical devices, blood transfusion should --or should not—be reported to the national authority, given the procedures in each country. In turn, management committees tend to deal with purchasing, accounting and procurement as well as servicing issues.

Concluding comments

In this paper I have discussed the major policy issues for regulating medical devices and presented the evidence to document regulatory transformations at three levels: global, regional in regard to the European Union and national based on the experience of two countries. I have also addressed the membership of policy networks, roles and responsibilities as well as accountability. However, beyond general information on the basic structure of implementation networks, the work has not yet progressed sufficiently to allow for a systematic comparison of policy networks

across regulatory levels and across the three countries nor for a systematic examination of the specific impact on regulatory outcomes.

Three handicaps are in the way of final conclusions. First, field work in Germany has not yet begun. Second, I need to better understand the link between the role of the networks of the stakeholders in this sector and the institutional arrangements or regulatory mechanisms through which regulatory policy on medical goods is enacted, mediated, refined, altered and/or adapted to different circumstances in each country. This applies regardless of whether we dealt with the macro, the meso and the micro-level. And, third, I need to better understand how the interplay between these networks and institutional arrangements--causal chains, if you will—relate to the outcomes. Once, this complex relationship is fully analyzed, better explanations may become possible.

Several observations are clear. The first stage of the implementation of European regulatory policy on medical devices has harmonized rules for cross-border trade, lifted restrictions on the movement of medical devices and began a process of revisiting implementation experience gained between 1993 and 1998. Stage two, in effect since June 14, 1998, has stiffened requirements for implementation on the European level and required more coordination of action across the European Union and the stepping up of implementation efforts in each country.

Global harmonization is a very distant goal given the co-existence of three regulatory regimes makes global regulatory convergence. Given the three economic power houses—EU, USA and Japan—global convergence is even unlikely. Despite global and European-wide regulatory convergence in trade matters, differences in handling the clinical, economic and social aspects of medical device regulation among them may even get bigger in the future.

For example, France and the United Kingdom have pursued a domestic policy requiring stringent evaluation of medical devices to prove efficacy and value added in comparison to existing diagnoses and therapies as a precondition to market authorization and as a precondition for reimbursement under each country's national catalogue of reimbursable procedures and items. Germany only lately has warmed up to the idea of stricter requirements in the legislated *Health Care Reform 2000*. The differences in approaches toward the implementation of regulatory requirements among the three countries are larger than expected. Rather than convergence, divergence in enforcement measures characterizes the implementation contexts in the three countries.

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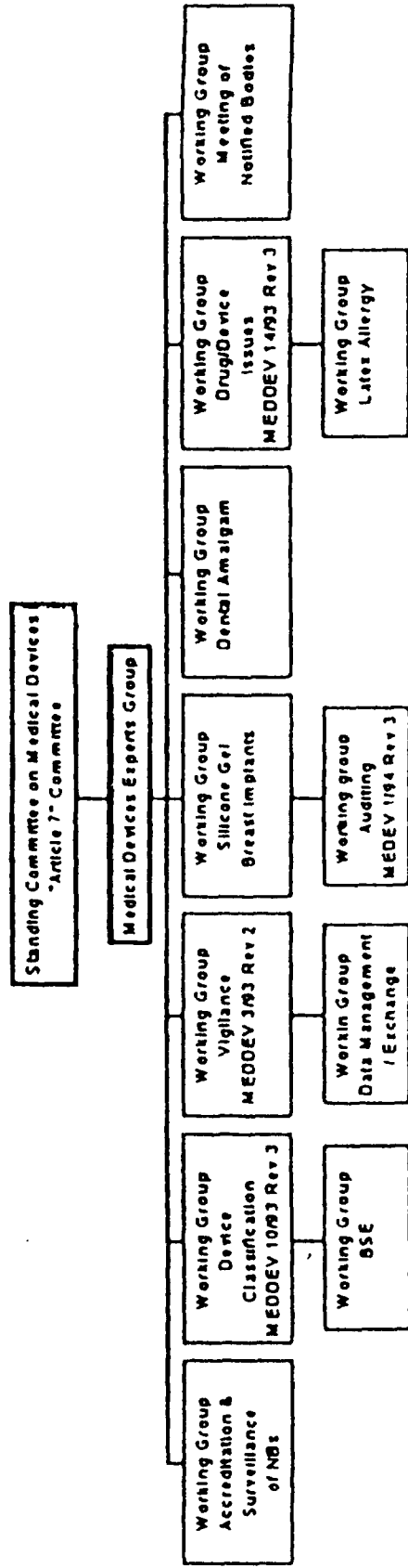
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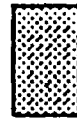
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EC COMMITTEES: Communication & Decision Making



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DG III + CAS + NBs + Industry



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FIGURE 1: OVERVIEW OF STUDY GROUP 1 WORK PROGRAMME

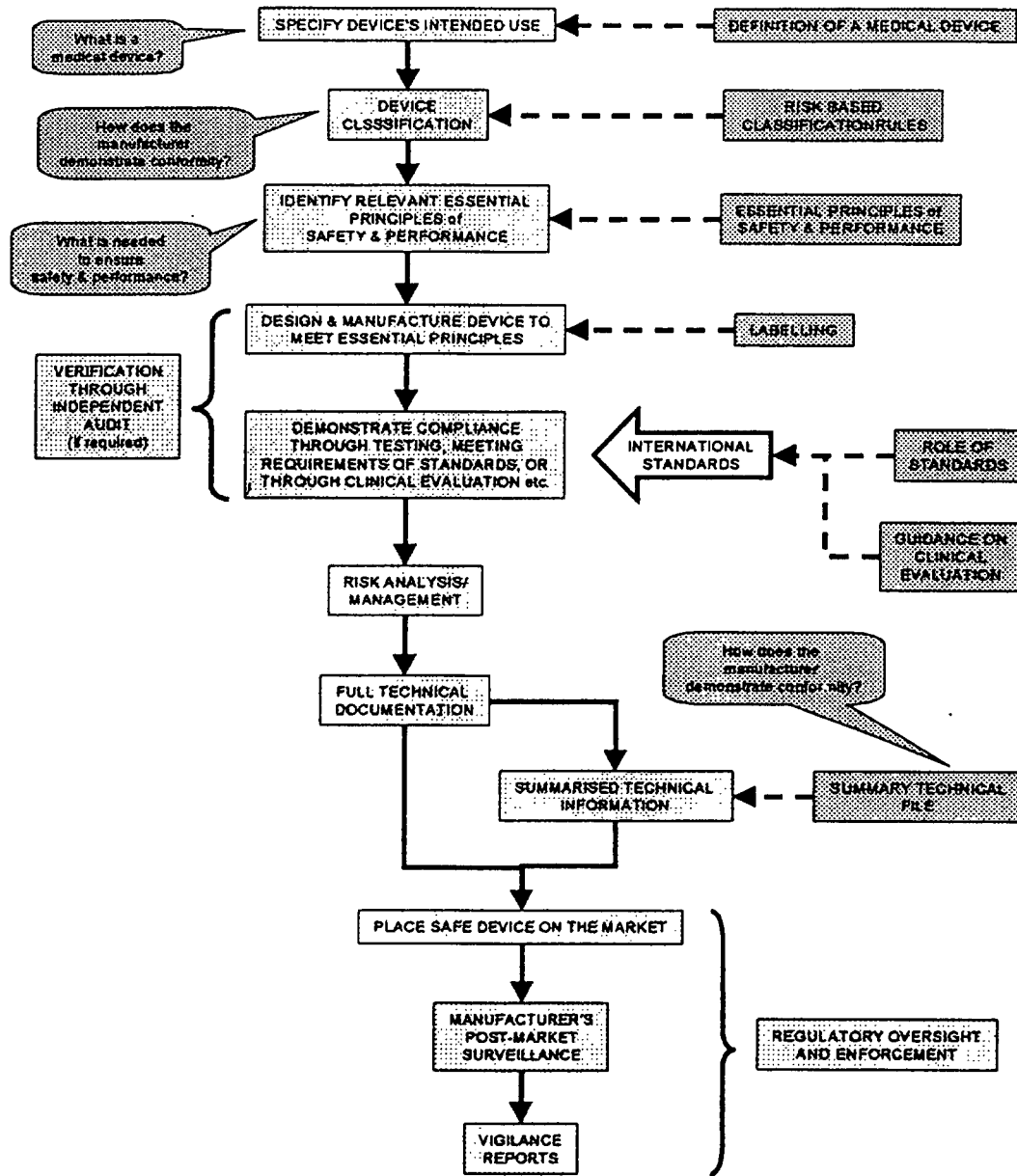


FIGURE 2: OVERVIEW OF STUDY GROUPS 2, 3 & 4 WORK PROGRAMMES

