Regulating healthcare technologies and medical supplies in the European Union: A comparative overview

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Abstract

A complex relationship exists among EU regulations, current national practices and rules, institutional capacities to implement regulatory adjustments and the legacy of past health and regulatory policy and traditions. However, there is little empirical information on medical devices policy, the medical devices industry, and the assurance of medical device safety and usage. Drawing on a review of the secondary literature and on-going field work, the evidence suggests that the current mix of state-centric and self-regulatory traditions will be as important in determining the implementation and final outcomes of EU-rules as the new rules themselves. EU directives redesign rules, but they do not necessarily lead to institutional change, create institutional capacities, or alter old practices in the short term. Neither EU directives nor national regulatory adjustments determine the "man-machine/skills-experience" interface which is shaped and influenced by local medical traditions and the acceptance of these traditions by local publics.

Key words: health care technologies and medical supplies industry; EU regulation; national and subnational implementation; stakeholders; convergence of a fiscal crisis; divergence of regulatory practices and cost containment tools.

1. Introduction

Since the early 1980s, the Commission and the European industry have argued that the competitiveness of the European medical devices sector is severely constrained by three major non-tariff barriers: (a) national health care policies, (b) national provisions on refunds for care, and (c) the limitations of small national markets (Commission 1992). EU institutions, and particularly the Commission, intend to liberalize markets and strengthen the competitiveness of European industry world-wide. However, if the Commission is serious in scaling back all non-tariff barriers, including those existing under national health protection schemes, it faces the immense task of reversing a historical trend towards an interventionist state in health care systems in Europe which has benefited the industry. Despite comprehensive regulatory controls of the delivery of health services, or more likely because of them, the European industry has maintained a symbiotic relationship with health care systems and protection schemes for the last two decades and has been one of only a few growth industries.

On January 1, 1995, a new set of European rules covering practically all non-pharmaceutical products, except implants and in-vitro diagnostics (clinical chemistry diagnostics) became effective in all member states of the European Union. While serving as umbrella directive for all medical devices, the medical devices directive (MDD) follows the new Union law on active medical implantables (AIMDD) in effect since January 1, 1993 in the member states. The two directives cover about 80 percent of all medical devices used in the EU and the countries of the European Economic Area. A "Draft Proposal for a Council directive on In-Vitro Diagnostic Medical Devices of April 1993 (IVDMDD)" finally led to the adoption of a common position of the EU Council in April 1995 and is

expected to be legislated on by the end of 1995 and come into effect in the member states by January 1998. At that time all technical standards are expected to be available and all directives transposed into national law in each member state.

Building on the European Union's new and global approach (Commission 1994) these three medical devices-specific directives aim to establish a unified statutory, regulatory and administrative framework for the first time in Western Europe. Regulatory policy as policy in general is best understood to mean what is actually done rather than what European and national policy actors claim will be done and what the law prescribes to be done. National actions presuppose the existence of control, enforcement and accountability structures, institutional capacities to carry them out, and an on-going flow of information and communication across a variety of public and private implementors in the national and subnational arena.

The implementation of these three directives is overlaid by the "acquis communeautaire" and the "acquis judiciel" (that is, current EU laws and court rulings). Sales and purchases of high-tech installations and equipment to hospitals (mostly public hospitals) are covered by the directive on public procurement. Other pertinent EU rules come into play in the implementation of EU-regulatory policy and include information procedures on the standardization of industrial production and products, the general product safety (GPS) directive, the low voltage directive, the machinery directive, the electro-magnetic compatibility directive, the directive on liability for defective products, product safety, the telecommunications terminal equipment directive and many others. Finally, there is the extensive legislation issued in the context of the creation of the single European market.

Although the MDD provides many detailed definitions in both the texts and the appendices, it is a complex matter to determine what a medical device is. The term medical device stands for a broad range of sophisticated health technology products, equipment and installations, surgical, medical and dental instruments and supplies used in patient care, patient-supporting appliances and aids. In-vitro diagnostic medical devices include reagents, technical instruments and diagnostic systems (combining both reagents and technical instruments). A few definitions remain highly controversial and contested. For example, the drug/device borderline issue remains a major bone of contention in an eight billion US dollar market of fictitious drugs and wound care. Issues surrounding human and animal tissues, confidentiality, labelling, custom-made or intermediate products, quality systems, risk analysis, subcontracting, technical files as well as medical waste and the eco-label are not any easier. An army of legal advisors, highly paid consultants, and many focus groups of European trade associations as well as judges are kept busy in Brussels and the member states giving legal and practical advice while continuing to develop workable definitions and solutions within the framework of the directives.

With increasing information technology in medical practice and clinical research, definitional issues are not getting any easier. Telemedicine is widely practiced in health care systems. A medical device can combine hardware and software that allow the connection of the device to any other computer or device via the public telecommunications network. If this is the case, the device is subject to the telecommunications terminal equipment directive (TTE). In other cases when software is installed, the information technology equipment directive (ITE) applies.

It will be argued that, even with unified European rules, national and above all subnational implementors have ample room to make strategic choices and to change or refuse to change their established routines. Redesigning rules is not synonymous with redesigning institutions, or creating institutional capacities. Rules do not necessarily change institutionalized behavior and action ((March and Olsen 1989) nor engrained organizational cultures. While those wishing access to European and global markets in order to sell their products and increase market shares are likely to adjust fast to the new circumstances, those who are responsible for enforcing compliance with post-market controls, the recall of deficient products and medical vigilance are probably slower to depart from past practices. This argument is further strengthened by the existence of significant policy connections between medical devices, the delivery of health care, the coverage of benefits and the reimbursement of providers for the use of medical devices in patient care by national health protection schemes. Medical devices are part of the globalization of production and technology. Yet their local use in patient care transcends the confines of production, R&D and sales and reaches deep into intra-health care affairs.

In an article of this length, it is not possible to follow up on every political development in Europe or individual countries which may be related to medical devices. Nor is it possible to confirm the second-thoughts which a few policymakers have voiced in the post-Maastricht era about the detailed and legally binding annexes which have had a few unintended regulatory rather than deregulatory

effects. The paper is limited to a discussion of the implementation of the medical devices-specific EU-directives and other EU-directives bearing on industrial products. It contrasts and compares the pharmaceutical and the medical devices industry. It reviews the regulatory practices in health care in Western European countries, provides an inventory of current distribution and purchasing practices, and identifies the major stakeholders in medical devices-related decisionmaking processes: governmental offices, suppliers, wholesalers, distributors, and doctors and hospitals. Finally, it concludes by drawing out a few lessons from the available information and suggests several research tracks for further study. If at this stage it is impossible to have all the empirical facts at hand, drawing on rich interdisciplinary literature (law, political science and public administration) and field work is justified as a necessary first step. In a second phase the formal, but above all, informal patterns of interaction between sellers, purchasers and users and their politics will be mapped and examined.

2. Approach

In elaborating about the implementation of EU directives in the EC member states and signatories of the European Economic Area this article integrates insights from two levels of implementation analysis: a (a) "top-down" approach on the national transposition of EU rules through national legislation; and (b) a "bottom up" perspective of implementation and company- and other organization-based implementation efforts which include purchasers, notifying bodies, monitoring organizations, distributors, retailers and sales representatives. In theory, the transposed national laws and ordinances provide the necessary prescriptions for implementation. In reality, implementation processes span several tiers of reality: macro-policy and structural; numerous policy linkages between the medical devices policy domain, the policy domain of national protection schemes and the industrial sector at the meso-level; and policy effects at care- sites: hospitals, nursing homes, doctors' offices and homes.

From a "top down view" the transposition of the two EU-directives into national law is almost complete. The AIMD is transposed in fifteen countries and the MDD in ten countries, while the AIMD is pending in one country and the MDD in seven countries (EUCOMED 1994-1995). Having completed to designate the competent authorities a few countries have reorganized the relevant organizational unit within the ministry of health. A few have organized authority and operational responsibilities for medical devices regulation out of the Ministry of Health and delegated them to seemingly independent organizations. Some have split the authority and operational responsibilities for adverse event reporting and clinical notification and others have not. In some instances, the authority and responsibilities for all functions rests under the same organizational roof. Brussels has been informed about the identity of notified bodies, their expertise and qualifications for all or a few modules only. Notified bodies are highly competitive and their promises in glittery advertisements are impressive.

With the laws and regulations in place and authority and operational responsibilities assigned, one should now expect faithful implementation. However, such view is simplistic because implementation is never a self-executing process. Actions need to be taken and decisions made, and legal, administrative, medical, ethical and/or social conflicts solved when and wherever these arise. Central decisionmakers frequently overrate their capacity to control implementation, steer the flow of information and communication, and often underrate the existence of problems on the ground. Implementation processes should therefore never be understood as automatic, linear and uniform.

From a "bottom up" perspective, implementation is far more complex. Beyond transposition, the implementation of EU regulation is mediated by public and private sector corporate actors dealing with medical devices and/or national protection schemes. They take action, make decisions and solve conflicts and in so doing can use multiple 'access', 'veto' and 'decision' points to their advantage when adjusting past practices to new EU-rules. A good many actions and decisions are contingent upon current national rules, administrative practices and the delivery, the financing and the reimbursement of health care in each country.

These legacies of financing, delivering and reimbursing for patient care and health governance, public administration and law are strong. Payers of health care, health workers, clinicians and those who monitor clinical investigations and adverse event reporting are influential intermediaries. Finally,

sellers, distributors and corporate sales representatives and the purchasers of medical devices form another cast of characters.

On the industry-side, the three medical devices-specific directives roughly correspond to three distinct industrial sectors: high-technological equipment and medical supplies, clinical chemistry diagnostics, and the electromedical diagnostic sector. Each has discrete attributes related to the nature and size of the industry, company structure, market shares, established distribution and sales practices, and volume, price and degree of risk of the products they sell or distribute. The directives cover premarket, market, and post sales-related processes: innovation and R&D in companies and laboratories, clinical trials, manufacture, sales, distribution, wholesaling and retailing and purchasing. The use and safety of medical devices fall primarily into the realm of health care delivery, with surveillance and medical vigilance cutting across health care and enforcement.

While an analysis of the political economy of each industrial sector is beyond the scope of this paper, a few observations can be made. The medical devices industry is a huge global market. In 1990/1991 the industry manufactured goods worth over $ 450 billion (Mathews 1993). The United States, the world's largest producer, accounts for 58 percent of world-wide production. Europe is the second largest producer, accounting for 33 percent, Japan is third with 8 percent. A similar pattern holds for the consumption and use of medical devices, with the United States consuming 50 percent of world-production, Europe 33 percent and Japan 13 percent. About a third of all biomaterials production in health technologies worldwide are manufactured by ten transnational companies (Willems et al. 1992:8).

In Europe, Germany is the largest market for medical equipment and supplies, with about 30 percent of the market. France accounts for 15 percent, the United Kingdom 12 percent and Italy 12 percent. Spain is the fifth largest market at 6 percent, followed by The Netherlands at 5 percent. The remaining EU and EFTA countries oscillate between 3.5 percent and 1 percent (Mathews 1993).

In 1993 the IVD market was a 4.6 billion ECU volume (invoice sales, EDMA) Germany had the largest market, with 27 percent. France and Italy account for 20 percent, Spain for 12 percent and the United Kingdom for 5 percent.

Until January 1, 1995, the intensity and density of regulation in European countries have varied considerably, and not every country has regulated each area. There have been different practices for securing the (a) the safety, quality and performance of medical devices; (b) product registration requirements; (c) inspection practices; (d) pre-market testing and certification (type-testing or type approval which is either compulsory prior to marketing or quasi-compulsory in view of connections with national health care delivery schemes); (e) post-sales controls and practices for servicing and maintenance; (f) medical vigilance and quality assurance; and, last but not least (g) vastly different patterns of participating actors from the medical devices policy domain, the medical industrial sector, the health protection schemes and the health care delivery systems. These actors have different authority and influence, pursue different interests and goals, and have different motivations and preferences which shape or constrain their game plans in response to new EU rules (Scharpf 1989; Ashford 1993:317-362).

The "quality instruments" of the new and global approach pursued by EU institutions and in particular the Commission include: essential safety requirements for different product groups. Certification of conformity of products with the essential requirements presupposes compliance with international or European standards specified for different product groups and risk classes. Compliance with the relevant CEN/CENELEC standards implies fulfillment of the essential requirements of the directive, and is a precondition for certification of conformity assessment procedures.

Medical devices are classified under four classes of risk: low (class I) intermediate (class IIa and IIB) and high (class III). High risk products are subject to more intensive verification procedures (including third party testing) than low-risk products. Both these risk categories and the specification of general and essential requirements continue to be controversial. Assessments of risk and risk-taking are highly subjective issues, and manufacturers, regulators, standardizers, and end users have different perceptions and tolerance for taking risks.

Two major types of uncertainty in the use of medical devices are in particular troubling: risks associated with the devices themselves (arising from the "man-machine" interface) and uncertainties of a general medical and professional nature (arising from a man-machine/skills-experience interface). Limited skills and lack of experience with medical devices are one cause of risks to patients and users.

Devices can pose risks to patients when they are diffused too early, when they are too old (eg x-ray equipment), when they are based on non-biocompatable and non-sterilized materials, when they are not serviced, and when they are over-or underpowered. Inadequate staffing, incorrect handling, and the lack of appropriate labels or instructions can also lead to hazards or misuse. While high standards for safety and quality, reliability of performance and minimization of risks are in the interests of all patients and users, critics argue that the EU-directives do not go far enough and leave too many issues unaddressed and unresolved.

Standardization and standards are the key to European regulation. Due to limitations of space, it is only possible to indicate briefly what is at stake. The strategy pursued by the Commission in the 1990s stresses standards for a broad group or family of products (horizontal) on labelling, symbols, biocompatibility, electromagnetic compatibility, sterility, good manufacturing practices (GMP), good diagnostic practices (GDP) and guides for clinical evaluation. Product-specific standards (vertical) were emphasized during the 1970 and 1980s, but by the early 1980s they were seen as inhibiting innovation, competitiveness and economic growth. Now they are to be used sparingly, but most standards for high-tech medical devices continue to be product-specific (eg MRI).

CEN, the European standardization body, is currently working on a workplan comprising about 140 European standards. Some 100 standards were mandated under the MDD and 40 by the AIMDD. Because of the wide variety of MD products, the CEN Technical Sector Board (BTS) 3 "Healthcare" has adopted a three-level approach under the MDD. Level I standards are basic standards, i.e. standards covering fundamental requirements common to all or to a very wide range of medical devices; Level II standards relate to group standards, i.e. standards relating to requirements common to a group or family of medical devices; Level III Product standards, i.e. standards relating to a particular type of medical device (Moore 1994).

The manufacture of high-tech installation, equipment and other electromedical products requires different technologies and component parts. In a global market, high technology components are frequently manufactured in one country and assembled with lower tech components manufactured in another country. This is of central concern to those concerned with product liability issues (Orgalime 1993) who prefer product- and part-specific standards for medical devices, although EU regulation makes standards and standardization voluntary. The additional uncertainty surrounding risk-levels for medical devices, as distinct from general medical uncertainty, blurs the lines between the de jure and de facto obligations of medical devices manufacturers, providers and other parties involved in patient care.

Standards are typically viewed as a technical, chemical and engineering matter. Yet they raise complicated economic, political and scientific and, in the case of medicine, cultural issues (David 1987; Schneider and Werle 1990, 1991; Schmidt and Werle 1992, 1993; Olshan 1993). Medicine raises cultural issues because medical technology is fundamentally cultural and contingent upon local medical school traditions (McPherson 1990; Kaufer 1992), providers' tastes and preferences, and social acceptance of these preferences. Yet, in an increasingly interdependent world, economic, political and scientific conflicts over quality and safety standards are likely to increase in importance. The crucial issue is whose standards and conceptual frameworks will guide the regulation of production sites and product standards and the distribution, sale, and purchase of medical devices in the 21st century.

3. The medical devices and pharmaceutical industry compared

Non-tariff-barriers for the medical devices industry are said to be as extensive and numerous as they are for the pharmaceutical industry. However, in contrast to a 25-year practice of regulating the pharmaceutical sector (Burstall 1991; Touche Ross 1991, Greenwood and Ronit 1991; Anderson 1994), the medical devices sector has not attracted the attention of European and national regulators until very recently. A certain view persist in some quarters as if medical devices and pharmaceuticals and the respective industries were similar. But extrapolating from the experience of the pharmaceutical industry with European regulation is risky for several reasons. First, the sector-specific directives for pharmaceuticals and medical devices do not share the same internal architecture, with their formats and approaches differing considerably. Second, the two industrial sectors are not identical, with important differences in company structures, distribution, wholesale and retail practices, and targeted

end users. While the pharmaceutical industry is fairly homogeneous, the medical devices industry is very heterogenous, although about a third of all medical devices are manufactured by about ten transnational companies which are not identical with the leading global players in pharmaceuticals. In some instances the boundaries between pharmaceutical companies and medical devices companies are actually blurred because some pharmaceutical companies have gone into lucrative medical devices production. Yet, in contrast to a few American companies which have gone this route, European transnationals are medical devices companies sui generis. In Europe, there are also many highly specialized medium and small enterprises (SMEs). Further, these two industries have organized their representation in Brussels and lobby on their own behalf in the countries' capitols and Brussels (Altenstetter 1994).

In light of these political and structural differences, the interaction between governments and export-dependent industries and individual companies is unlikely to play out in similar ways across the two industrial sectors at all levels of decision making on policy and rules: national, European, and international. The goals and interests of manufacturers of active implantables, highly sophisticated health care technologies and clinical chemistry, to name a few, are not identical. Some produce single, highly expensive items and others high volume, low cost items while serving different clienteles at the same time. Finally, and most importantly, national health care policy, macroallocation decisions on resources and cost containment policies have affected the two industries in different ways. For some time now, pharmaceuticals have been at center stage in cost containment efforts. Medical devices are not yet drawn into a thicket of regulation, although capacity and location planning has limited the diffusion of expensive technologies. A major controversy persists about the extent to which medical devices come under the reach of pharmaceutical regulation. The persistence of this view is reflected in the ways in which a few countries have organized authority and responsibility for medical vigilance and post-sales monitoring.

4. Regulatory practices in health care in context

Historically, industrialized nations have employed a mix of six major methods of regulation: nationalization, hybridization, administrative regulation, public agency regulation (preferred in the USA), self-regulation and regulation within firms and groups (Wright 1993). With the exception of public agency regulation, all other forms of regulation are found in Europe's health care systems, with distinct "regulatory and administrative cultures" and recently, "management cultures." These health care systems are also embedded in societies with different notions of the polity, the state, common law and Roman law (Dyson 1980; Bogason 1991, Majone 1994; Metcalf and Richards 1993). Even different "safety and quality philosophies" have been identified across the EU countries relating to occupational health and safety regulation (Eichener 1993; Joerges 1988, 1992) and environmental regulation (Vogel 1986).

In the European tradition regulations and governmental rules have primarily been about social goals rather than efficiency, including securing health as a social good rather than as a commodity, imposing controls in the public interest, and conflict management. Only secondarily are they about efficiency. The understanding of "effective governmental rules" by economists squarely contrast with rule-making and rule-adjudicating which invoke values, politics, conflict resolution and law.

The last decade has seen changes in the nature of the state which has been "hollowed out" at three distinct levels, with some variations across countries (Peters 1993). These changes include a loss of legitimacy at the macro-level, decentralizing program delivery at the meso-level, and a diminished role for officials at the community level. Health care reforms have followed similar developments. Reformers in, for example, the United Kingdom, Sweden and The Netherlands established "internal markets" within national health services schemes, introduced a few competitive elements in national health protection schemes such as in Germany, changed the management of regional and local health authorities and altered the relationship between public and private management (Jéô.-Forget et al. 1993; Eliassen and Kooiman 1993). However, the evidence does not suggest that these reforms have overridden the distinct and recurring patterns of public and private sector management in Anglo-Saxon, in contrast to continental European, countries and replaced country-specific patterns of behavior and attitudes.

4.1 Prescriptions for the delivery, financing, reimbursement, and regulation of health services

One of the features of European regulatory controls over health care is that controls are applied at the macro-policy and sectoral levels which affect provider and user groups in uniform ways. Even the previously mentioned "internal markets" and "competitive elements" operate under the umbrella of national policies. Where the "public model" applies, state agencies at the central, regional/district, or local level formulate and implement regulations and monitor compliance and accountability. Where the "self-regulatory" model is practised as in Germany and the Netherlands, corporatist or associative actors control decision-making, implementation, enforcement, and accountability, including quality assurance and medical audits.

A substantial body of literature (too numerous to be listed here) links national health policy, government, interest groups, and institutions and discusses the changing role of the state as payor, regulator, owner and employer in several western European countries and speak to the convergence which has occurred in the interaction between markets and government, church and state, industrial relations and ownership, entrepreneurship, sales and commerce and the medical profession. Yet, despite fairly similar policy reactions, interventionist legislation over long periods of time and and continuing interaction of state regulators and provider markets have produced variations in each country. Even similar responses to rising health care costs have not produced the same results (Abel-Smith 1992).

The last two decades have also seen an increase of macro-controls on volume of services, prices, budgets and capital investments and the breadth and depth of the effects they aimed to achieve. With resources for health care becoming scarcer everywhere and competing with other public goods, the volume of regulation is unlikely to shrink. Recent cost containment policies and strategies have added new layers of regulatory controls such as aggregate spending targets and caps, global budgets. These controls contrast with the language of "internal markets", "competition among purchasers," "competitive incentives," and the like.

All European countries have experienced financial crises in health care spending so demand-side restrictions have become more popular with European policymakers, although they are nowhere as common and extensive as in the United States. In the United Kingdom, the Netherlands, Germany, and Italy, costs are being shifted to consumers by increasing copayments through a variety of cost-sharing methods. National reformers are all too eager to find advocacy coalitions to support a reduction of the public share in health care financing. Whether they privatize medical resources, introduce competition inside national health services, "manage" care or privatize health risks through increased copayments and deductibles, there has not been an escape from regulation.

The delivery of hospital care in practically all EU countries rests on multi-tiered hospital-based service arrangements, with different providers working in either the public or the private hospital sector (Massion and Schutyster 1993; Glaser 1987). Lately, outpatient services have been added. The delivery modes are negotiated and bargained by teams representing hospitals and the buyers of hospital services. Over the last twenty years state institutions have intervened in the supply of hospitals and hospital beds by guiding the geographic and functional distribution of high-tech medical resources through hospital planning and location planning (OECD 1990; 1992).

The delivery of hospital care is the responsibility of each member state (or regional and county/local governments) and will remain so in the post-Maastricht era. Public hospitals are now subject to the directive on public works and the public procurement directives. With information technology, computers and telecommunications penetrating into doctors' offices and hospitals, the practice of medicine is being revolutionized. Telemedicine and computers and information technology have far-reaching implications for patient care and patient data management, hospital management and organization, internal quality assurance schemes, purchasing practices and many other intra-hospital non-medical services. They hardly make regulatory controls obsolete.

The last decade also has seen the development of all kinds of legislated or self-regulatory quality assurance schemes for the delivery of quality health care based on the individual responsibility of the medical profession (Jost 1990) and hospitals, and include institutional review boards (IRBs) and "human subject" commissions. Quality assurance programs are a direct result of the proliferation and use of new and unproven medical technologies, the use of old and obsolete medical devices and cost containment efforts.

A recently published eight country-study of health care technology assessment provides valuable comparative insights into macro-controls of the pharmaceutical and the medical devices sector (Health Policy 1994; Banta and Luce 1993). While it fully confirms the significant differences of policy and implementation of pre-and post-market controls of these two sectors in all eight countries, it also speaks to the different stages of development which the two industries find themselves in. But the study does not address the subnational implementation of public policy and the interactions between purchasers and users (that is, surgeons, clinicians, health care workers or even patients) on the one hand and corporate sales representatives, distributors and retailers on the other.

4.2 Medical devices regulation: from production sites to distribution, sales and procurement.

The scope and content of the regulations bearing on medical devices are less intensive and far-reaching than those for health care delivery, finance, reimbursement, pharmaceuticals, manpower and services planning. Even in the few countries which for some time have had medical devices-specific rules on the books like France and Germany (perceived to be "the most highly regulated country") and the United Kingdom which enforced regulations in the absence of specific legislation, the regulatory reach was limited. The Scandinavian countries and The Netherlands have been involved in medical technology assessment and monitoring of technology for some time. For the majority of European countries, however, building up manpower and institutional capacities is now required. A few countries have regulated the disposal of medical supplies and medical waste. Still fewer have enacted rules concerning in-vitro medical devices. In a five-country comparison of law and practice (France, Germany, Italy, Spain and the United Kingdom) Maassen (1991:2) found a high degree of inconsistency and lack of homogeneity in existing national regulation of IVD-products. He writes: "At the one hand of the scale, Germany has the most comprehensive regulation of IVDMD, followed by France which occupies a middle ground. At the other end of the scale are countries with only little or practically no regulation relating directly to IVDMD: Italy, Spain and the United Kingdom. Legal requirements, if they exist at all, for IVDMD, which can be roughly divided into reagents, technical instruments and diagnostic systems (combining both reagents and technical instruments), relate separately to reagents on the one hand and to technical instruments on the other."

Table: B
Relative strength of state regulatory intervention, 1980

4.3 Coverage for quality care and medical procedures.

In most western European countries, access to health care means entitlement to high-tech diagnosis and treatment, patient-supporting devices and medical aids paid for by health protection and accident-at-work schemes, with various arrangements for copayments and deductibles (BASYS 1991:79-83; 1992a, 1992b). Public coverage for these products is limited to about 75 percent (EC-average). In contrast, public coverage for high-tech treatment of inpatients or outpatients is about 97 percent coverage (EC average), or 90 percent in doctors' offices (J ösx1990:88). The average percentage of bills paid by public insurance for hospital care and ambulatory care is considerably higher than for medical goods and patient-supporting aids. Belgium, the Netherlands and Spain limit eligibility for these items (J ösx1990:89). In several countries refund policies for the same item (eg wheelchair) vary under health care protection and accident-at-work protection schemes.

4.4 Spending on medical appliances and aids.

Most comparative analyses neglect to examine the relative share of national health care spending on medical appliances and medical aids and dental services. Yet, taken together, these two areas form a significant component of per-capita and GDP spending in most countries. Spending on dental services is close to or even higher than spending on prescription drugs. In contrast, the percentage of GDP spent on medical goods in 1989 was modest. But most OECD member states have shared one experience. From 1960 onward, public coverage against the costs of medical goods has been

expanding (OECD 1990:145). Expenditures have accelerated everywhere due to the needs of a growing elderly and disabled population, low cost equipment and patient-supporting aids. The use of innovative technologies in medical practice and minimally invasive surgery, improved post-operative care and more effective implants and prostheses and increasing consumption sooner or later will attract the attention of health policymakers and cost conscious payors and buyers of health care.

4.5 Controls on volume, services and medical procedures.

In the past, Western European countries have engineered ways to curb demand for health care by controlling the volume of services and their utilization. The first is achieved through the selective exclusion of diagnostic and therapeutic services. For example, the British NHS limits eligibility for hip replacements, renal dialysis and heart transplants by age. Most countries have limits on physical therapy, and the number of days that can be spent in hospitalization, rehabilitation, etc.. Open or covert rationing is the most drastic form of limiting services. If pressures on health care budgets continue to rise, it will be important to examine more systematically how decisions to exclude diagnostic and therapeutic medical procedures from reimbursement are made, who makes them, and the effects such decisions have on providers and patients.

A second type of control is achieved through a variety of copayments by consumers/patients. Copayments are seen as distorting prices and restricting markets for medical goods as well as inhibiting innovation and development. Unlimited coverage is seen as providing incentives to increase demand for medical procedures, patient-supporting appliances and medical aids. On the other hand, the inclusion of medical technologies (procedures) in reimbursement schedules guarantees high turnover, sales and profits. With an increasing use of certain medical devices, even at home, the issue of appropriate pricing of medical devices and reimbursement under public programs may come under closer scrutiny everywhere. Charges of overpricing are sometimes heard, including exaggerated fees for leasing equipment like oxygen machines at home. Differences in payment methods between accident-at-work schemes and health protection schemes eventually may be evened out.

Four types of copayments are paid for medical appliances, patient supports and aids (MPS 1990):25,35-37,43-47). The most prevalent method is a percentage payment, which is used in nine countries. The remaining countries use fixed amounts. The exclusion of diagnostic and therapeutic procedures is practised in five countries (Belgium, Italy, NL, Germany and Ireland). The following therapies or products are excluded from health protection schemes: Kuren (Belgium), contact lenses, contact lens cleaner (all in Germany), prosthetics, orthopaedic shoes, hearing aids and eyeglasses (Italy, Netherlands), and baths and massages (Netherlands). Finally, three countries (Belgium, Ireland and United Kingdom) use some fixed copayment for specific products (eye frames, prosthetics, hearing aids.

4.6 The cost of administering legislation and the regulation of medical devices.

Information on spending for high-tech equipment, medical
supplies, medical aids and patient-supporting devices is quite limited. Record-keeping remains a function of the respective health care system and reflects its particular division of labor between the hospital and non-hospital sector, the range of combinations of public-private delivery systems, reimbursement methods, etc.. As a result, administrative accounting has a long way to go before systematic data are available for comparisons (Poullier 1992). Poullier argues that administrative costs for health care are higher than typically recorded in most OECD countries. This argument is persuasive. The private sector shoulders the bulk of the cost of administering pre-market controls, including standardization, and post-sales controls which do not show up in national accounts. Costs for capital equipment, machinery, maintenance etc. seem to be "hidden" in global budgets, accounting arrangements and national accounts for public administration.

5. Missing information about selling, purchasing, distribution and retailing practices

Two pressures are simultaneously at work in the implementation of EU-regulations: globalization of production and technology and national cost containment policies. This section presents a profile of the major stakeholders leaving an in-depth analysis of resolution of these dual pressures for later field work.

5.1 Purchasers.

Independent practitioners of office-medicine usually seem to purchase their medical supplies and equipment directly from distributors and/or networks of corporate sales representatives. Companies do engage in so-called 'ethical marketing' and follow some codes of conduct. But the conditions under which distributors and/or corporate sales representatives advertise and sell their products to doctors, laboratories and hospitals are not well documented. Some companies are known to use networks of salespersons with excellent contacts to medical specialists and hospitals. Building on these contacts they do not need to advertise their products. Recently, the international and national press and the payers of health care have spoken of bribes, corruption and scandals in several European countries. The companies keep silent about sales strategies and data on sales, profits, innovation and development nor do they reveal reliable data on R & D on medical devices. (Statistisches Bundesamt 1992:65-66).

Another group of purchasers, far more important in terms of the value of sales, turnover, and use, are public and private hospitals, other health care facilities, clinics, rehabilitation facilities and residential homes. Often, installations and equipment are not purchased by the individual facility but by a variety of non-medical procurement officers and government offices (OECD 1991:87). Categories of buyer groups include:

Physicians: GPs, specialists and subspecialists
Mixes of public, not-for-profit community hospitals, and for-profit clinics
Central university hospitals
Regional medical schools
Municipal hospitals
Small- and medium-sized hospitals
Acute and long-term hospitals for the chronically sick and disabled.

In the past, each country applied its own sets of rules, norms and procedures to guide decision makers on procurement, purchases, tendering, the development and monitoring of performance and descriptive standards.

5.2 Decision makers on procurement.

Recent health reforms have altered procurement practices in national health systems and in particular in the British National Health Service. The EU directive on procurement requires new methods of purchasing and procedures which will have to be adjusted by a variety of responsible offices and bodies who in the past were responsible to decide on procurements. Based on information in trade journals and intelligence reports procurement decisions were made by:

* central authority(ies);
* regional health boards, Lä=â, county councils;
* local governments;
* individual hospitals and hospital boards;
* individual physicians and specialists;
* purchasing agencies buy directly;
* a central purchasing board handles purchases for all/some hospitals;
* a central authority approves the preselection of equipment and medical devices and a hospital equipment boards of area health boards implement the purchases.
* most purchases need to be authorized because

the majority of equipment is paid through government grants.

Depending on the value of the equipment, the location in old or new hospitals, and the ownership: public or private hospitals, the procedures to follow differed.

Tendering was handled as

* open tendering published in the official journal;
* closed tendering with control of state agency;
* selective tendering (registered suppliers are invited to bid);
* annual or bi-annual supply contracts on the basis of recommendations that products be bought only from registered manufacturers;
* "hidden" "buy local" procurement policies.

Requirements for performance and descriptive standards needed to follow these procedures:

* medical equipment must conform to national standards which follow European (EN) and international standards (ISO and IEC);
* electro-medical equipment must be approved by a national certifying body;
* equipment must be tested prior to approval by a central authority;
* electric appliances must be registered with a national board;
* certain medical products must be approved by the Ministry of Health;
* national standards are issued for certain products for use on patients (e.g. surgical implants, renal equipment, catheters and infusion products);
* products must be registered with a national authority prior to introduction onto the market;
* products must be registered with a national authority prior to import:
* safety tests must be implemented prior to introduction onto the market;
* special safety standards for handicapped aids;
* limited approval of operating high-technology equipment with periodic renewal.

While a few practices and procedures have been or, will have to be, adjusted at the highest policy level through legislation (eg the transposition of the annexes and the modules), subnational implementors will be asked to make many other changes.

5.3 Suppliers, retailers and distributors

Suppliers, retailers and distributors are important intermediaries between the industry and the buyers. But little systematic work is available about them. Since January 1, 1995, they can only sell and distribute products which meet the essential requirements of European rules and meet international or European standards to secure safety in all care settings. Full implementation of these directives also requires changes in the handling, storage and transportation of medical devices. As previously mentioned, high tech equipment and medical supplies are purchased in a variety of ways, but little is known about the ways in which decisions on purchasing medical devices are made and about corporate sales strategies and existing wholesale and retailing practices, except for insiders. Partial evidence suggests the existence of important differences between countries which pay different prices for the same products. There are differences between individual companies in their sales strategies and interactions with clinical specialists and surgeons. The major groups of buyers, decision makers and distributors are identified below. These are

* approved national suppliers;
* importer/distributor: general/specialised and small/large;
* individual agents;
* exclusive agent to cover the whole country;
* local distributors engaged in re-exporting
* activities;

* local manufacturing and sales of subsidiaries of multinationals;
* sales subsidiary of domestic manufacturers;
* foreign sales subsidiaries;
* collaboration with local manufacturers making non-conflicting products.

Case studies could yield insights into the politics of sellers and purchasers when contracting and subcontracting. But they are not available.

6. Implications for research and concluding comments

This paper grew out of an interest in understanding the extent to which the new EU-rules on medical devices are implemented in the member states and what regulatory adjustments are made in highly regulated and complex health care systems in western European nations. Since January 1, 1995, two out of three directives are now in force, signalling the beginning of a new era in medical devices regulation for the industry and manufacturers, health care providers, patients, payors and purchasers of health care. Whether the Commission softens its views on the negative effects which national controls on pricing, fixing fees, restricting the volume and consumption of services have on technological innovation, discovery and the competitiveness of European industries, is uncertain at this time.

Changes in copayments or deductibles for medical care commodities, the exclusion of medical procedures, the introduction of "internal markets", competitive elements in health protection schemes and the further privatization of health risks require a good many new regulations. While cost containment strategies may constitute major barriers to free trade of sophisticated technology and medical supplies in the European Union, these are in the interest of governments and all domestic payors of health care: tax payers, contributors to public or private insurance and consumers. It is in everyone's interest to continue to stabilize domestic health care expenditures. From this perspective, the idea of abolishing non-tariff barriers and leaving a resolution on prices, fees, volumes and services to market forces seems impossibly ambitious. Yet the political rhetoric about market forces is appealing but also highly misleading.

Unless European countries are willing to pay more than 25 percent of every dollar for administrative costs compared to the current range of between 6 and 10 percent, and 14 percent of GDP for health care rather than the current range of between 5 and 8 percent, lifting these controls on prices, fees, volumes, services, the distribution of expensive technologies in the office- and the hospital-sector and geographic and functional capacity planning would be foolish and counterproductive. The fiscal crisis, widely debated and documented, doubtless points toward convergence. Yet, past regulatory practices in health care and preliminary findings of medical devices regulation point to considerable divergence in pre-market, market and post-market controls. If European societies start with substantial variations in rules and practices concerning the use of medical devices, rather than their manufacture, convergence is unlikely to be achieved soon.

Mutual recognition, home country controls and standards development reveal traces of these distinct "regulatory, administrative and management cultures" in the handling of pre-market controls and post-sales monitoring. The centrality of state-centric and self-regulatory traditions in health care is difficult to undermine, although health care systems are undergoing substantial reforms while the role of the state in health care is also being redefined. In the presence of strong policy legacies in all aspects of health care the relationship between EU regulation, current national practices and rules, unequal political and administrative capacities to deliver national legislation and implement regulatory adjustments make it unlikely that while accounting for comparable cases EU regulation will produce the same outcomes.

Whether uniform European rules will bring all manufacturers the savings expected from harmonized Europe-wide rules is also unclear. Some manufacturers in highly specialized and local markets who intend to go global or Europe-wide first will have to bear additional costs. Those who expect that a unified statutory, regulatory and administrative framework will produce the desired effects seem to overlook what Foote (1992: 216) so dramatically pointed out as hindering innovation and development of medical devices in the United States. She writes: "The manner in which the policies are crafted and implemented leads to effects on the device industry. These effects may be

further influenced by the interactions of various policy prescriptions." While she is on target in suggesting that inconsistent and incoherent policy prescriptions produce adverse effects and often undesired outcomes, the implication that the logic of universal access to high tech medical procedures in patient care is irreconcilable with the logic of cost containment and the logic of industrial policy is fundamentally challenged. Despite an array of regulatory controls on price, volume, budget and investment in Europe over the last twenty years, the medical devices industry has been one of few growth industries in Europe and globally.

Dramatic developments are taking place in health technologies industries and delivery systems everywhere. Industry- and medical profession-driven developments are revolutionizing the delivery of health care. Global markets for innovative and complex medical technologies are emerging for the first time on an unprecedented scale. Computer and information technology are adding new speed to the transformations under way in patient care, billing, accounting and research. Some research and expert communities, buyers of health care and state administrations are riding high on the information highway and in cyberspace.

The key issue for the future is how the tensions between liberalized markets and globalized production and technology will be resolved while retaining or securing universal health care as a social good at the same time. The answers depend on whose value premises win out in global high technology competition, and how the pressures for local cost containment are reconciled with the globalization of healthcare production and technologies and the liberalization of trade. Much will also depend on how different nations balance the needs of patients/consumers and users for high safety and quality requirements against the needs of export-dependent industries. To resolve the competing claims of competitive organized economic and political interests is a highly conflictual political process.

Short of systematic research beyond the rhetorical and symbolic aspects of regulatory policy, there is no simple way of knowing exactly what actually happens on the ground. Research needs to be pursued along several tracks. It must clarify the role and impact which past approaches in the EU member states have had on recent choices and reorganizations in order to implement the EU-directives. Research ought to look into what the notified bodies, those who certify conformity with EU regulations, and those who monitor MD-, IVD- and AIMD-products are actually doing, and examine whether they have changed routines in reality rather than on paper only. Research needs to clarify the politics surrounding the choices by national regulators in designating testing houses, and how these choices may influence the decisions of manufacturers to submit requests for conformity assessments and CE marking (conformit éeuropéó>) in one western European country rather than another. Research should monitor the progress made in reducing the "windows of uncertainty" arising from the use of medical devices, and how and whether the new European-wide information exchange networks and medical vigilance system work, and what regulatory data, if any, are exchanged among the member states. With community and home care being emphasized practically everywhere in the advanced industrial world, it would be another task to examine how countries handle equipment maintenance at home, in doctors' offices, hospitals and nursing homes, and who is responsible and accountable to whom.

The exact financial burdens of the cost of purchasing technology and their use in patient care are not knonw on the basis of available data and accounting schemes. The information on the cost of surgical, medical and dental equipment, machinery, instruments and supplies need to be improved. There are significant differences in charges for the prescription and non-prescription medical care commodities
across Europe. There are no unified accounting schemes across Europe nor unified and refined product classification schemes. Finally, the contribution of health care technologies to the improvement of quality care and quality of life should receive systematic comparative attention as well as the medical devices industry as a labor market.

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