Healthcare reform in Germany in comparative perspective, with special attention to funding and reimbursement issues of medical and hospital services

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Prepared for delivery at the 29th ECPR Joint Sessions of Workshops, Grenoble, France, April 6-11, 2001. Workshop No. 15 *Health Governance in Europe: Europeanization and New Challenges in Health Policies.*

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Introduction
During the decade of the 1990s, healthcare reform has been on the political agenda, with four pieces of reform legislation and regulatory interventions addressing different aspects of the German statutory health insurance (SHI). The conservative Kohl government introduced the first phase of reform measures with the Cost Containment Act in 1989. The second phase started with the Health Care Structural Reform Act of 1993. When the Social-Democratic-Green coalition headed by Mr. Schröder came to power after the elections of September 27, 1998, it adopted the Act to Strengthen Solidarity in Statutory Health Insurance (SHI) in late 1998 and, in December 1999, a revised and slimmed down version of the Reform Act of SHI 2000 (Healthcare Reform 2000). All reform packages dealt with cost containment, the restructuring of the financing of medical and hospital services and the restructuring of SHI.¹

This paper first provides a historical-political explanation of the German health insurance program by defining the demarcation lines—though somewhat blurred—between historical continuity and change in national SHI policy and programmatic orientation. It then focuses on the most recent reform measures and in particular on hospital financing and the reimbursement of medical and surgical procedures. However, in order to generalize, the German case has been placed in a comparative perspective drawing on information from France, Germany and the United Kingdom, howsoever broad the brush for the comparison must remain leaving an in-depth comparative investigation for a later date.

Why focus on reimbursement issues of medical and surgical procedures and hospital funding? The answer is in three parts. In reimbursement issues it can be shown that coverage decisions on medical and surgical procedures in a national benefit catalogue raise a new dimension in patient access to medical innovations—a topic largely ignored in cross-national research. Second, it can also be shown how a European Union policy dimension and a home policy dimension are simultaneously at work in funding and reimbursement issues. The single European market and the need to meet the convergence criteria under a single currency combine to impose new regulatory requirements and constraints on healthcare systems, as on the welfare state as a whole. Third, decisions on market approval of medical goods and reimbursement issues require clinical and economic evidence assembled by different actor groups and largely clinicians and policy analysts. Final decisions on this evidence are made by distinct policy actors participating in separate decision-making processes. Yet they do follow specific procedures distinguishing between evidence being submitted for market approval of a product, and in an organizationally separate step, for inclusion in a national benefit catalogue. But the evidence from the first round counts toward final decisions in the second round. A different mix of stakeholders is in control of these separate though intersecting processes. Whether the result are
policy coherence and consistency or, contrariwise, policy contradictions and inconsistencies is an empirical question that cannot be answered in this paper.

This paper on healthcare reform in Germany is part of an on-going cross-national project on the impact of European regulatory integration in France, Germany and the United Kingdom. It seeks to find out how the creation of the single market may undermine or alter—though not necessarily dismantle—the social model of health care, and why the single market may—or may not—be driving a nail into established solidarity-based models of health care in Europe. The comparison is grounded in three types of literature: historical-empirical institutionalism, domestic implementation research, and regulation, which provide the primary lens through which the impact/implementation of EU directives and national adaptation is examined and information gathered.

France, Germany, and Britain are useful cases for a focused comparison of national and sub-national implementation. They were chosen for a number of reasons. They are all parliamentary democracies, share a common tradition of public administration and civil service bureaucracy and, on this basis, have developed distinct national regulatory styles. They are the three leaders in European Union regulatory developments in the medical devices field while sharing the same responsibilities and obligations in implementing EU policy intentions in compliance with three medical device-specific directives.

As to the healthcare system, they share a commitment to solidarity and universal (UK and France) and near universal coverage of the population (Germany). However, they differ along a number of crucial variables pertaining to macro-policy and macro-structures of the political-administrative and the healthcare system, with France having employer-based public insurance plans, Germany since the mid-90s public competitive insurance plans and the United Kingdom having a centralized National Health Service. All three countries have established distinct rules of the game and follow distinct "principles, norms, rules and decision-making procedures" (Krasner 1983) for the purchase, financing, and siting of heavy and expensive medical equipment in the past. Their approaches to regulating the behavior of the scientific and clinical communities responsible for the diffusion and use of medical products and quality assurance in the ambulatory and the inpatient sectors differ.

The three countries employ different methods for reimbursing doctors and hospitals. In each country, the regulation of prescription drugs has preceded the regulation of medical device by two decades. And to the extent that each country was regulating some aspects of medical devices (e.g. heavy equipment, siting and operation of specialized services) prior to European regulation, such domestic regulation was largely embedded in the prototypical pharmaceutical regime.
Given the distinct paths to the present that each country has taken and the policy packages that current governments have inherited from their predecessors in each country, the implementation context in each country is assumed to start from a different point of departure. Ultimately, the combination of path-dependent and new policy factors will shape, though not determine, the ways in which these three countries respond and adapt to EU regulatory policy.

**Design and Methods.** The premise for data collection is clear. In order to understand the implementation process and the impact of healthcare reform on delivery sites, one must go beyond the aggregate macro-policy level. Data collection needed to proceed from the macro-level through the meso-level (institutional arrangements) down to the delivery sites (micro-levels). On this basis, over 100 semi-structured and open-ended interviews were conducted in France in 2000 and more than 40 were conducted in the United Kingdom in 1999. The transposition of the field notes is completed. However, interviews in Germany have not yet begun.

Building on past (Altenstetter, 1998a and 1998b) and on-going research, this project primarily uses qualitative methods and draws on secondary analyses, public documents and an array of “grey” literature. Routine data on national healthcare systems (NHI and NHS) and routine information systems in each country hardly provide data and information on the functioning of institutions in charge of reimbursement issues, the impact such decisions may have on the outcomes of healthcare reform, and the ways in which they filter, mediate, modify or adapt policy on health care reform. These data tell us little about the attributes of policymaking process nor about the coordination process by which national policy positions are coordinated in order to speak with one national voice at the EU level.

The evaluation of the performance of healthcare reforms and their impact on delivery sites continues to be difficult in each country. Routine process data and public administrative data in the UK, France and Germany are limited for this purpose. As Haas (1998) argued for the European Union as a whole, data on compliance and enforcement of national and European Union directives are entirely missing. The data collection of field information has focused on interviews with informed and knowledgeable individuals close to the formal and informal implementation process in each country, and with academic researchers and major sponsors of legislation.

**Historical-political developments in Germany: A Recap**

The institutional development of medical care policy in Germany has followed a unique historical path. During a long process of growth and social experimentation, Germany combined a vigorous and highly competitive capitalist economy with a social welfare system that, with some exceptions, has provided its citizens with generous benefits and services. The system’s benefits are so extensive that by the 1990s annual total spending by the state, employers, and
private households was DM 407 billion (US $ 200 billion, or 11.5 per cent of GNP. Adding expenditures for sick pay, this amount rises to DM; about DM 526 billion or about 14.9 per cent of GNP (Pfaff and Wassener, 2000, p.908). Unlike many of the world’s advanced countries, however, Germany does not provide its citizens with health care through a centralized state-run system (*Subsidiarität*). Rather, it provides these benefits via a complex network of federal agencies and a large number of independent regional and local entities—some public, some quasi-public, and many private and voluntary. Many of these structures date from the nineteenth century and some from much earlier.

The legislation that established the basis of this system dates from the 1883 and was passed by imperial Germany’s parliament, the Reichstag, with the dual purpose of helping German workers meet life’s vicissitudes and thereby making them less susceptible to socialism. This legislation set the main principles that have guided the development of medical care policy in Germany to the present day: membership in the national health insurance program is mandated by law; the administration of the health insurance program is delegated to nonstate bodies with representatives of the insured and employers; entitlement to benefits is linked to past contributions rather than need; benefits and contributions are related to earnings; and financing is secured through wage taxes levied on the employer and the employee.

Germany’s national health insurance program was developed from the bottom up. It first covered elements of the working class and then extended coverage from about 20 per cent of the working class in 1883 to ever broader segments of the population—today more than 90 per cent—and incorporated additional risks along the lines of medical progress.

There is sufficient evidence to confirm the validity of a path-dependent development to explain most elements of a 150-year history of SHI in Germany. First, SHI survived the shift from imperial Germany to the Weimar Republic in 1918, then from the unstable Weimar Republic to the Nazi regime in 1933. The formation of two Germanies in 1945, respectively 1947, resulted in two different political and healthcare systems. In East Germany, a centralized state-run system was put in place, and physicians became state-employees. In West Germany, the pre-war system was reestablished. It was supervised by the government but was not state-run. After the unification of Germany in 1989, a wholesale transfer of institutions, rules, and procedures from West to East Germany occurred. In addition to SHI, West German hospital laws were superimposed on East Germany. On January 1, 1991, SHI began to operate in the Eastern states. To everyone’s surprise, East German physicians made the transition to fee-for-service medicine more rapidly than expected and abandoned their employed status. Whether the political cost for changing the path was too high, or whether policy-makers at each critical juncture acted in a crisis situation, normative and operational principles have survived these four drastic regime changes.
According to the Basic Law of 1949, Germany’s constitution, the federal government has exclusive authority in public health insurance matters and sets broad policy for NHI. The federal government’s authority applies in particular to these policy elements: benefits, eligibility, compulsory membership (today with the potential to change fund membership) covered risks (physical, emotional, mental, curative, and preventive), income maintenance during temporary illness, employer-employee contributions to NHI, and other central policy issues. However, except for the financing of hospitals, the responsibility for administering and providing health care has been delegated to nonstate entities, including national and regional associations of health care providers, Land hospital associations, nonprofit insurance funds, private insurance companies, and voluntary organizations.

During all these periods, German healthcare policy has shown a remarkable degree of continuity in organizational arrangements and financing. Change has been largely of an incremental nature, and new elements have conformed to previously existing principles and patterns. The German case shows that each successive regime change produced “path-dependent, self-reinforcing historical sequences” of prior decisions on healthcare policy and the reimbursement of providers and financing of health care (Pierson and Skocpol 1999). Yet, there is also evidence to suggest that a path-dependent process initiated in the late 19th century cannot explain current elements of change during the last decade and still evolving, which may qualify as “non-reinforcing sequences.”

With a perceived escalation of health care costs since the mid-1970’s, the need to macro-manage the financing of medical care and micro-manage the reimbursement of providers has tremendously accelerated during the last decade. The Health Care Structural Reform Act of 1993 has reproduced the organizational and regulatory status quo. Yet it also launched substantial restructuring such as the setting of regional budgets for medical (Schwartz and Busse 1996) and hospital services in 23 regions in Germany, the reorganization of sickness funds, and the reform of the hospital sector (Busse and Howarth 1999). The latest reform culminated in radical shift from retrospective cost-covering to prospective case-based flat reimbursement of hospitals (Altenstetter 1999, pp.66-81).

The Reform Act of Statutory Health Insurance 2000 (SHI 2000), as its predecessors have added more elements to both macro- and micro-management of medical and hospital services (Busse 2000). Given the demographic, epidemiological and technological transformations—occurring in all advanced societies—is healthcare financing and medical progress sustainable and compatible in Germany? Specifically, can Germany continue to finance healthcare services under the conditions which Germans have taken for granted during the past forty years? Is solidarity-based financing of medical care an Auslaufmodell? The answer is ambivalent.
A recent report from the German Institute for Economic Research (DIW) in Berlin shows that developments in medical technology will contribute significantly more to rising healthcare costs in Germany than will Germany’s ageing population. The authors of the study, Breyer and Ulrich (2000) extrapolated up to 2040 from an annual rise in health expenditure which they identified as 1 per cent in 1970. The report shows that the level of patient contribution to NHI will rise from 13.5 per cent of today’s salaries to 23 per cent of salaries then. Taking out the effects of improvements in diagnosis and therapy, the contribution levels would only rise to 15.5 per cent of salaries. The authors argue that German health-policy makers are underestimating the effects of medical innovation and technology. If politicians continue to miscalculate the rise in contribution levels, the authors argue, this could result in regulatory interventions in more frequent intervals than the average of four years when major legislative and regulatory interventions were enacted.

The political environment. Parliamentary elections of September 27, 1998, resulted in a change of government from the Kohl to the Schröder government. Fast thereafter the Social Democrat and Green coalition adopted The Act to Strengthen Solidarity in Statutory Health Insurance (SHI) in late 1998 reversing earlier decisions on ever increasing patients’ co-payments. The law reduced patient cost-sharing burdens and reintroduced sectoral budgets in the outpatient and the inpatient care sectors. Although the Schröder-led coalition has abandoned its traditional view that patient-co-payments are unacceptable and should be kept to a minimum, it has accepted co-payments as a politically acceptable tool to contain rising health care costs.

The political process surrounding Healthcare Reform 2000 provides two lessons. The first lesson is this. To win elections on health issues when the public continues to be fully supportive of solidarity-based health care (Busse 1999) is difficult. During the 16-year reign of conservative chancellor Kohl, the general public did not support the reform measures, particularly those enacted under the leadership of Mr. Seehofer, the last minister of health before the electoral defeat. Until then, cost containment policy had focused on the supply side rather than on the demand-side for medical services. Under his leadership cost-sharing and co-payments were strengthened and imposed. However, it is quite likely that the elimination of dental coverage for young Germans and increases in patients’ co-payments hit a sensitive nerve with the public. In September 1998, Kohl lost the election. The implied cause and effect relationship between the public’s high priority over health and electoral defeat needs empirical verification.

There is a second lesson. In the past, federal politicians have been able to push through reform measures against the opposition of physicians, but they have not been able to push through reform measures against the opposition of the Land governments. Because of their resistance, including social-democratic led regional governments, the more ambitious plans
concerning the control of expenditures on drugs, dressings, revamping the hospital sector and doctors’ salaries, which were introduced in SHI Solidarity Strengthening Act in late 1998, and expanded by the proposed draft bill for SHI 2000, had to be dropped when on November 29, 1999, the Federal Council (Bundesrat) flexed its muscle and vetoed Healthcare Reform 2000 in its original 102 page-long version.

The powers of the Federal Council are considerable and quite unusual when compared to the second chamber in other federal systems (like the U.S. or Swiss). The federal construction in Germany implies two potential dynamics, with implications for a shifting balance of power between the Bund and the Länder and for securing a continuously strong role of the regional governments over national health policy development. First, a majority coalition government elected for a four-year term may face a majority of opposition governments in the Länder in the second chamber resulting from 16 Land elections. The Bundesrat has used its veto powers extensively. So-called zustimmingspflichtige Gesetze (agreement laws) can be adopted only with the approval by the Bundesrat. If the latter does not approve, elected officials have to resort to political manoeuvres by redrafting a piece of legislation or a federal ordinance in such a way that the approval of the Bundesrat is no longer necessary in order for a federal ordinance to become effective. This was the case with The Reform Act of SHI 2000. Second, under German federalism, the views of the Länder governments are taken into account from the very beginning of the legislative process. Draft legislation is introduced by the federal government first in the Federal Council before it is passed on to the lower house (Bundestag). Examining social policy in Germany in the federation Münch (1997) concludes that even welfare state legislation could not shift the balance of powers in favor of the federal government and away from the state governments.

Given these two factors–coalition government and federalism–for 12 years (from 1969 to 1981), the Bonn SPD-FDP coalition did not command a majority in the Bundesrat. Federal and regional elections between 1981 and 1993 placed the CDU/CSU-FDP in the federal government’s driver seat while putting the SPD in the federal opposition and reversing also the control over regional governments. The Kohl government led the federal government for sixteen years from 1983 to 1998. In 1992, the interests of the federal and the Land governments in fiscal federalism converged for the first time even though they were controlled by different political majorities. The Bund and the Länder feeling the effects of German unification on their respective budgets agreed on reforming the allocation of resources in Germany. The SPD-Grüne majority could rely on its allies in the Länder from September 1998 to the elections in Hesse in 2000(month?) when the CDU resumed a majority position in the Bundesrat.

The way ahead: more micro-management of delivery sites. The shift from retrospective cost-based reimbursement to flat-rate reimbursement per patient independent of the
type or volume of services provided is a shift in the method of financing hospital services of historical importance. In a path-dependent development specific to the hospital sector in Germany, this shift constitutes a critical juncture, although flat rate payments were introduced in 1995. However, the latest reform touches on coverage decisions for pharmaceuticals and the reintroduction of a positive list of reimbursable drugs, which was bitterly opposed by the pharmaceutical industry in the past. It introduces for the first time a positive list of medical and surgical procedures in hospitals in Germany which could mean the de-listing of some procedures from the benefit catalogue. New procedures can also be added to the catalogue.

Clearly, the utilization of medical technologies, evidence-based medicine and patient access to the latest therapeutic treatments are significant. These topics are no longer under the legal monopoly of corporatively organized medicine and insurers. Rather, they are now on the legislative and executive agenda. Hence they share decision-making authority with elected policy-makers and civil service in varying degrees. Politically, these are highly sensitive issues sparking passionate debates among the major stakeholders: clinicians, the pharmaceutical and the medical device industry, the payers of medical and hospital care, as well as politicians and bureaucrats in Berlin and the capitals of Land governments. The pharmaceutical industry has been a powerful force in all these debates for quite some time. By contrast, the medical device industry with a high potential for medical innovations is becoming visible. However, the medical device industry in each country along with the European medical device group (EMDG) is on the defensive. Their honeymoon with regulators has terminated, and the respective trade associations have difficulties in convincing payers and buyers that medical technologies can be cost-effective when compared to established medical and surgical procedures included in the benefits catalogue. So in each country, industry wants a seat at the table when coverage and evaluation decisions are made.

The debate over Healthcare Reform 2000 in Germany clearly showed “historical persistence” of the arguments which each stakeholder group made. At the same time one discerns a certain cognitive dissonance between organized medicine, the medical device industry and payers in Germany about how to improve healthcare services. The medical profession insist on an independent evaluation under its exclusive control. From a patient perspective certain treatments and self-help and patient supporting devices that are beneficial to patients in daily life are unnecessarily restricted. For example, hydro wound dressing is an innovative way for wound healing and avoiding bed sores in home and institutional care. However, it is not included in the benefits catalogue in Germany. The same applies to single use devices which are safer but more expensive than the multiple use of medical devices. A cheaper alternative is sterilization of medical devices with high risks of infection when sterilization is handled inappropriately. This problem is widespread in today’s hospitals in Germany, France and the United Kingdom.
During the period of 1984 and 1996, the use of coronary artery stents for patients who suffer from asthma and coronary heart disease and standard procedures of coronary angiography and percutaneous transluminal coronary angioplasty (PTCA) experienced an enormous diffusion in Germany. As Perleth et al. (1999a and 1999b:757) report, “Germany took the lead position in terms of both the absolute number of procedures and the rate in Europe. This included coronary angiography and PTCA.” The absence of a formal process of HTA in Germany until January 1, 2000 made it possible that PTCA and angiography could diffuse without major constraints when compared to HTA processes established in France (Durieux et al. 2000) and the UK (Smee 2000) since the early 1990s.

Finally, regardless of how one views the methodology employed in the WHO World Health Report. Germany’s ranking as # 25 on the world list of WHO (when compared to France as # 1, UK as # 18 and the USA as # 37) raises a number of critical issues about the performance of the German healthcare system, its cost-effectiveness and overemphasis on curing disease and underemphasis on health promotion and disease prevention. Change will come with difficulty unless a new powerful alliance of stakeholders emerges in the future with the political will to act in order to redefine the allocation of financial burdens, establish a new balance in the relationship of SHI and private health insurance (PKV), and secure patient access to medical innovations for all people in Germany.

II Health policies and patient access in Germany

Over the last decade, healthcare reform in Germany has pursued several strands: cost containment, a policy on quality and patient satisfaction, and HTA and clinical practice guidelines. Sustainable healthcare financing and access to medical innovations through sectoral budgets (hospital, ambulatory and prescription drugs) and flat rate pricing of hospital services since Healthcare Reform 2000–effective as of January 1, 2000-- present major challenges for stakeholders and patients alike. While recent reform measures may have equalized the conditions for physicians and hospitals, they may also jeopardize sustainable patient access to the best therapeutic treatments and diagnostic tests.

Healthcare Reform 2000 introduced several innovations. First, it set up two new national committees with broad ranging responsibilities in HTA: a new federal hospital committee and a co-ordinating committee. The new federal hospital committee (Bundesausschuß Krankenhaus), composed of the federal doctors’ chamber (BAK, 4 delegates), the national association of sickness funds (9 delegates) and the German hospital association (5 delegates) will review medical procedures used in hospitals.ii If a coverage decision on a medical procedure is negative, it will not be reimbursable under the SHI.iii A co-ordinating committee will have to develop binding evidence-based guidelines for 10 indications each year.iv This committee will also make recommendations for the work of the new hospital committee and the existing “NuB”
technology assessment committee, which evaluates diagnostic and therapeutic procedures in the ambulatory sector.\textsuperscript{iv}

From 1949 until 1990, financing diagnosis and treatment that were medically necessary and economic (Wirtschaftlichkeit) was a guiding principle of medical care policy. The shift to clinical practice guidelines constitutes another critical juncture in the development of hospital policy. German doctors prefer voluntary guidelines as long as they represent scientifically-based recommendations of best practice over legally binding guidelines. They seem to have lost part of this battle. Eventually, the legislator may address professional and institutional liability issues.

In late 2000, the three parties to the hospital committee, submitted a new contract between the ministry of health and the three parties for approval and signature and countersignature by all parties involved. The parties will split the financial cost of setting up an office to manage the work of the hospital committee (50 per cent by the sickness funds and 25 per cent each for the hospital association and 25 per cent for the doctors’ chamber). Despite this agreement, there are differences of opinion between the payers and the medical profession. The sickness funds want a large agency with as many as 50 full-time employees while the medical profession wants to keep the cost of the committee down as much as possible. Physicians also fear that any guidelines from the committee will encroach upon clinical freedom.

The global budgets for each sector which were introduced in 1997 were renewed under stricter conditions than those existing previously. The federal ministry of health set the annual growth rate for each sector – hospitals, office-based practice of medicine, and pharmaceutical products. \textit{In toto}, in 2000 the annual growth rate was set at 1.43 per cent in Germany (1.63 per cent in the western states and 0.19 percent in the eastern states).\textsuperscript{vi}

Second, with a delay of more than a decade when compared the United Kingdom, France and other neighbors, federal legislation established the conditions for healthcare technology assessment of medical procedures and technologies. Emphasis will be placed on efficacy, effectiveness and cost (see comparative discussion in III).

Third, the legislation introduced a total overhaul of the financing of German hospitals from retrospective cost-based reimbursement to payments based on diagnostic-related groups (DRG). The German legislator left the decision which type of DRG to adopt to the national association of sickness funds and the German Hospital Federation (\textit{DKG}). They submitted their proposal to the ministry of health on June 27, 2000, just in time to meet the deadline before the ministry of health would have determined the DRG type by June 30, 2000. Corporatist decision-makers chose the Australian-Refined DRG system (AR-DRG) which will come into force on January 1, 2003.\textsuperscript{1} This DRG type was acceptable to the \textit{Länder}, both owners of hospitals and

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The AR-DRG is supposed to be operational in 2003 and fully up and running by 2008. It builds on the existing DRG-based reimbursement system of hospital care which was introduced for the first time on January 1, 1995 on a restricted basis. Then, some 40 DRGs and 160 operations were to be reimbursed by a flat fee. This constituted 25 per cent of in-patient hospital costs; the remaining 75 per cent were reimbursed in full. The new AR-DRG consists of 661 DRG. Each DRG represents a class of patients with similar clinical conditions requiring similar hospital services. Within each patient class, further differentiations according to illness, co-morbidity and complications can be made. After all adaptations from the Australian to the German DRG system are made, Germany is likely to have over 800 patient groups.

**Hospital reimbursement.** Even before the demand for EBM was put into law, self-government bodies had put into effect some measures that affected all healthcare sectors. On January 1, 1999, reimbursement codes were redefined and fees for a broad range of services cut. The cuts affected 32 DRGs and 76 negotiated fees and in particular in the cardiac and orthopaedic surgery. An industry insider (Mr. Sullivan) reported that rates for cardiac surgery were reduced by as much 22 per cent and DRGs rates up to 23 per cent. Fees for the replacement of an artificial hip were cut by 12 per cent and the fees for artificial knee implants cut by 25 per cent.

**Outpatient reimbursement.** Prior to April 1, 1999, the material costs associated with balloon angio-plast procedures were reimbursed on an invoice basis. Now they are limited to DM 2070 (US $ 1,150).

**Laboratory reimbursement.** On July 1, 1999, the federal corporatist association of office-based doctors (KBV) implemented a reform of laboratory reimbursement in order to reduce by 15 per cent special laboratory tests and services performed by laboratory doctors. The German Diagnostic Association (VDGH) reported that the actual cut was more than 36 per cent when compared to the same month the previous year. The volume of fees paid to laboratory specialists went down by 46 per cent. The effect of laboratory reform has been a shift of costs to the hospital sector. Special laboratory tests in hospitals are reported to have increased by about 27 per cent in hospital pediatric wards, about 50 per cent in oncology departments and about 22 per cent in the emergency units of internal medicine departments.  

Fourth, providers and sickness funds can directly enter into contracts without having to go through their respective corporatist associations. In theory, this option has existed since 1989 when the Health Care Reform Act was adopted and the debates about integrating outpatient and inpatient care intensified. In practice, there were many implementation deficits, although the
political mandate to the respective *Land* associations of sickness funds, physicians and hospitals to negotiate new public contracts was clear. However, because interfacing the two care sectors required coordinating investment decisions, any progress entailed negotiations with the *Länder*, which control capital expenditures for hospitals. The Health Care Structural Reform Act of 1993 therefore required the regional bargaining and negotiating associations of doctors, hospitals and sickness funds and the responsible *Land* agencies to do what they had failed to do voluntarily.

Yet regional variations in complying with the original intent of the 1989 legislation have existed.

Delays and shortcomings in the implementation of hospital financing laws are not new phenomena (Altenstetter, 1985, 1999). Similar deficits are likely to delay the operation of the new reimbursement system. Three major hurdles exist. First, many contracts and agreements will have to be reached on definitions and criteria within tightly set deadlines. By September 30, 2000 accounting principles and definitions must be available (are they?). The basic AR-DGR system requires adaptation to conditions in Germany. It requires translation into German. A comprehensive coding scheme for diagnoses, procedures and other grouping criteria is to be completed by November 30, 2000. Costing weights and the levels of markups and markdowns are to be agreed by December 31, 2000. A second hurdle which is conflict-prone is the strengthening of a gatekeeper role of general practitioners. Separate budgets for GPs and specialists remain. Patients receive a bonus if they consult a GP rather than consulting a specialist directly. However, patients are entitled to consult a specialist directly. The third hurdle is the operation of a new accounting system. The German hospital association estimates the initial cost of DM 100 million ($45 million) and a further DM 20 million annually to maintain the DRGs. There was talk of a DM 0.30 surcharge on each hospital treatment.

*Healthcare Reform 2000* intends to make hospital services cheaper. Decision-making on reimbursement is supposed to become more transparent. Yet, the new Hospital Committee and the Co-ordinating Committee are to discuss these issues in strict confidentiality and only the final results will be published in the Federal Gazette (*Bundesanzeiger*). This reinforces the chronic lack of transparency in decision-making by corporately organized bodies of sickness funds and doctors. The law intends to produce an efficient use of money and better care through competition. It also promises to reduce the length of stay in German hospitals which, by international standards, still is long.

Jörg Robbers, the managing director of the German association of hospitals, pointed out that 10 percent of German hospitals may have to close within the next ten years. He spoke to a fundamental contradiction inherent in the reform. “On the one hand there is a desire to encourage competition within the hospital sector, while on the other we still have sectoral budgeting. These two factors are clearly contradictions of one another....The DKG is of the opinion that neither
global or sectoral budgeting has a role to play within the new DRG system. Self-governing bodies have prepared the solid foundation for the new system, it is now up to the politicians to make the running,” he said. Quality management rather than sectoral budgeting is seen as the key to the success and operations of the new system in order to avoid the trap of “quicker and sicker.”

The German trade association (BVMed) has supported the reform insisting that the new system be a “flexible pricing system for hospital services, capable of adjusting to the developments of costs, and for the rapid and regular adaptation to medical and technical advances to be guaranteed.” According to the executive director of the medical device trade association in Germany (BVMed), Joachim Schmitt, some reform measures are actually impeding patients’ access to medical innovation. “Budgeting by sector and globally, is damaging to innovation” as it halts medical advances and conceals the threat of rationing.”

The problem for health insurers is that they have a fixed, one year budget. Some medical devices, however, only begin to become cost-effective after a period of three years” said Mr. Schmitt. “Patient access to innovative products, if necessary for their treatment, was vital. Products and treatments, such as minimally invasive surgery, could slash inpatient recovery time, which would also help reduce long-term hospital stays, cut cuts and thus justify the acquisition of innovative-if more expensive-devices.”

The German Medical Technology Forum has favored Reform 2000 although its spokesperson Dr. Christof Steimel (Forum Medizin Technik) warned against “underinvesting and underfunding” in the German healthcare system. He said: “It is crucial that the new reimbursement system allows room for investment and does not degenerate into a budget allocation tool.”

Among the expected consequences of this latest reform package are:

- increased hospital specialization and concentration of capital-intensive technologies in special centres;
- downward pressure on the price and quantity of supplies;
- incentives for hospitals to increase spending on capital goods that reduce operating costs;
- incentives to use cost-saving procedures and procedures that reduce the length of inpatient stay;
- decrease of the number and intensity of ancillary procedures; and
- encouragement of the utilization of extramural care, especially in the home care sector.

In conclusion, the answers to these open-ended questions are contingent upon a number of uncertain factors. It is unclear when the sectoral budgets in the hospital will be abolished and when the DRG system will be up and running. It is also uncertain if and when Germany will increase controls on the demand for more care, given the demographics. The federal legislator is likely to introduce new co-payments and German hospitals will insist on volume discounts when
purchasing medical products. Further, the introduction and management of the new hospital accounting system is bound to cost money but for some time we will not know how much. Finally, the effects of expanding the concept health to an all-encompassing concept well-being which has occurred within the last few years is bound to have financial consequences but the payers are reluctant to share this information with the public.

III Evidence-based reimbursement in comparative perspective

The analytical and cross-national story of healthcare technology assessment (HTA and evidence-based medicine (EBM) have been told elsewhere and need not be repeated here (AGREE 2000; Lohr et al. 1998; Garfield and Garfield 2000). For all three countries the question no longer is if and when demands for HTA and EBM are coming. Rather, the issue is the extent to which medical and surgical procedures in the ambulatory and stationary care sectors will be subjected further to tests of good medical practice and cost-effectiveness than they have been in the past.

Payers and evaluators consider HTA and EBM to be appropriate tools to optimize the allocation of resources and secure access to innovative treatments while also recognizing the contributions of medical technology to: diagnosis, promotion of health care, treatment, monitoring and care. However, due to a variety of complex factors that this paper cannot address, one effect of recent policy-making is certain. More restrictive evidence-based reimbursement of medical and hospital services will materialize faster than expected and faster than evidence-based medicine will be practiced primarily due to the resistance of medical professionals to follow practice and other guidelines. The enforcement of compliance with medical devices-specific EU directives on the one hand and domestic cost containment policy on the other are the major driving forces.

During the last decade, payers of healthcare have had a dominant voice, and they are powerful participants in decision-making on healthcare reform everywhere. They have left their fingerprints in the politics of healthcare policy-making and specific legislative and regulatory interventions (macro-policy). Payers have insisted on restrictive global and regional budgets and cost containment measures. Where central government controls existed such as in France and the UK, the payers and their political allies have been instrumental in making HTA and cost-effectiveness key factors in determining reimbursement levels of medical and surgical procedures.

Both countries took up HTA about a decade and a half earlier than Germany did. Clearly, the creation of ANDEM in France in 1990 was the beginning of a national HTA process in France. ANDEM was responsible for quality assurance and the development of consensus-based clinical guidelines. ANDEM’s mission was enlarged and now encompasses accreditation and evaluation. In 1996 ANDEM was regrouped under the National Accreditation
and Evaluation Agency (Agence Nationale d’Accrediation et Evaluation ANAES) in 1998/98 (Poullier and Sandier 2000; Durieux et al. 2000). The work performed by ANAES and the National Institute of Clinical Excellence (NICE) in the UK and various predecessor bodies (Smee 2000) shows the head start they have had over Germany.

With a delay of ten years, payers and health policy-makers in Germany now have joined the international healthcare community. In the words of a source close to the Swiss HTA process “the sleeping beauty of HTA has finally woken up in Germany,” and Germany is fast catching up with the neighbors (König 1998). This international community demanded evidence-based medicine (EBM), clinical practice guidelines, expert consensus, etc. as a basis for domestic decision-making and was successful elsewhere in Europe. In Germany, medical guidelines and standards in hospital care became a political option under the Schröder government. However, this does not mean that Germany did not have any quality assurance programs in the office and the hospital sector in the past. A voluntary quality assurance program has been run by corporate medicine (Weisner 1995) on a voluntary and non-binding basis. Corporate medicine organized quality circles, consensus conferences, inter-laboratory comparisons in laboratory medicine, guidelines for pharmacotherapy and special training programs for diabetes patients. The Reform Act of SHI 2000 now provides a legal basis for the creation of a formal health technology assessment process that will affect clinicians, hospital management and ambulatory care providers.

Three authors, who are among the few evaluators of medical technologies in Germany, argue that HTA in Germany to the extent that it has been practiced has been effective (Busse, Hoopman and Schwartz, 1999, p. 647). They reach two conclusions. First, evaluation “serves as an effective gatekeeper for health care. Twenty of 53 technologies were evaluated and proven of no added value for different reasons.” However, unlike NICE and ANAES, the German evaluators are more skeptical about HTA citing advantages but above all disadvantages for medical and technological innovation.

In the future, the German Institute for Medical Documentation (DIMDI) will be responsible for HTA. But its work will not be easy. Major problems are limited staff and a severe lack of valid, reliable and comparative clinical and health economic data and information which results in part from the legal monopoly of organized medicine and sickness funds over health services data and in part from the limited interests in HTA in Germany until recently. By contrast, the central government in France and the United Kingdom seems to control the flow of information on healthcare and healthcare financing. Central governmental controls adds legitimacy to HTA and EBM and facilitates policy coordination among the treasury and the ministry of health.
In France and in the United Kingdom payers of healthcare and regulators of medical goods require clinical and economic evidence as prerequisite for market approval and reimbursement decisions although in France the new process and the new decision-making bodies responsible for one or the other are hardly in place (Morisett 2000). Most medical and economic evidence comes from manufacturers and clinical trials, but payers and regulators are becoming more demanding and restrictive. Sources close to the respective sectors say that available evidence for pharmaceuticals is higher than for medical devices and surgical interventions. Procedures undergoing clinical trials in Germany are exempt from the new legal provisions on technology assessment.

Concerns for evidence-based medicine and medical outcomes analysis are also spreading from the macro-policy and macro-structural level down to the delivery end of care. Regional decision-makers (meso level) have to decide on the allocation of funds among hospital services, research and education, and the allocation from one type of disease or segment of the population to another. Individual care settings (micro) serve as laboratory for evidence-based medicine and how to maximize available resources for individual patients. In all three countries the demand for quality hospital management is in politically. However, the full impact on local sites is not known.

**Funding and reimbursement.** For reimbursement issues in general we need to distinguish between the use of technology in medical services in hospitals, doctors’ offices, home care technologies and handicap aids. This distinction is important independent of whether one defines reimbursement as third party funding of medical technology through the hospital budgets without being invoiced separately to NHS or NHI or separately based on per diems or flat case rates. The use of medical and surgical devices is reimbursed as part of medical procedures recognized as reimbursable in the benefits or reimbursement catalogue of NHI or NHS. Typically, reimbursement of hospital services covers the price of the medical device, equipment, operating costs and accommodation and comes out of the hospital budget. Reimbursement levels, if any, and prices and discounts are negotiated agreements between payers and the industry where, however, the payers dominate.

In the past, all three countries have engaged in similar strategies to contain costs:

- per diem and case rate (in Germany until January 1, 2000/2003; case rate in the UK)
- global budgets (public hospitals in France and the UK); global regional budgets in hospitals and a mix of flat payments, departmental per diems and basic per diem covering all non-medical costs until 2000/2003 in Germany).
- flat rate case-based payments introduced in Germany on January 1, 2000 and operational after 2003.
- a national catalogue of reimbursable procedures (TIPS) was terminated on July 10, 2000; the new framework of the Service Medical Rendu (SMR) for medical devices will be phased in and will be modeled after the prototype of pharmaceutical regulation. SMR
applies to French private clinics and general medical practices but is not yet operational for public hospitals.

However, short of further analysis, it is difficult to assess the influence of institutional mechanisms on the evaluation of medical and economic evidence for purposes of market approval and reimbursement. It is equally difficult to know the linkage between existing institutional mechanisms and final outcomes and consequences. The institutional mechanisms for evaluation and accountability, embedded as they are in distinct political and administrative-legal traditions, are country-specific. Each country has institutionalized separate decision-making bodies for market approval and reimbursement issues involving a distinct set of players in each decision-making process. Although the bottom line of much recent healthcare policy has been the containment of costs, it would be difficult to conclude that the policy actors involved played the same game of politics and followed the same “logics” in making decisions.

**Germany**
- Outpatient care: committee of physicians and sickness funds make ambulatory coverage decisions; reimbursement of providers by capitation;
- Inpatient care: old: per diem rates, flat rates for 25% of in-patient procedures; new: changes to DRGs and flat based rates for 100% of in-patient procedures by 2003/2008; simultaneously budgets are capped.

**France**
- Public hospitals: devices used in hospitals paid out of global budgets.
- Ambulatory care/private hospitals: evaluation for reimbursement by transparency commission and price fixing committee
- Physician office: fee for service

**UK**
- Devices used in hospitals paid out of global budget
- Potential appraisal by NICE

**A European dimension.** The connection between evidence-based reimbursement, cost containment policies and cost-effectiveness requires further explanation. Although the interaction between EU policy and home policies needs more detailed analysis than can be offered here, demands for evidence-based reimbursement and cost-effectiveness also have an origin in European directives. Funding and reimbursement issues can no longer be examined solely through the lens of domestic politics, although it is difficult to sort out one influence from the other. A strict legal reading of the Treaty of Rome, as amended by the Treaty of Maastricht of 1992, and again by the Treaty of Amsterdam of 1997, leaves reimbursement and pricing issues in the jurisdiction of the member states. Even a strict reading of the three medical-device specific directives (AIMD, MDD and IVDD) does not challenge this interpretation.
Yet the need for complying with EU medical device-specific directives provided a “unique window of opportunity” for France and to a lesser degree Germany, both with an insurance-based healthcare system, to fundamentally restructure existing evaluation, reimbursement and accountability processes. How this mix of European and national elements influences decision-makers and ultimate outcomes present a few puzzles which eventually will need to be further unraveled, described and explained as does the funding of heavy hospital equipment subject to European procurement rules superceding national rules.

Europeanizing and nationalizing regulatory processes are unfolding simultaneously. Yet they differ in terms of the actors involved, organizational mechanisms and the dynamics involved.

Prior to European market integration, manufacturers in most product sectors were not concerned about marketing and selling their products in Europe. Over time, each manufacturer had learned the ropes of heavily regulated markets and adapted sales and marketing strategies in each country according to the prevailing regulatory framework.

With the dynamics generated by the single European market, itself driven by global market integration, the honeymoon between the industry and national health care systems was over. In the post-war expansion period from the mid-1960s to the late 1980s, friendly relations with health administrations and public insurers provided them with many advantages and monopoly supplier status in many instances. After the creation of the single European market the industry reconsidered its strategies.

When national policy-makers, under the pressures of payers and purchasers of medical goods, began to look at medical technology as a cost-driving factor, the souring of their relations began and intensified. The medical device sector is the last item in the national health healthcare budget to have come under close scrutiny in each country. High-cost technologies and pharmaceuticals were subject to heavy regulation for some time, with France having the strictest regulations imposed by la carte sanitaire followed by the UK and Germany (Battista et al. 1994).

After hesitating, if not blocking action in Brussels for about three years, in late 2000 Germany has joined the leadership of France and the United Kingdom. On the European level these two countries had insisted on stricter regulatory requirements for high-risk products and a revision of the EU medical device directive (MDD of 1993) for some time. Since Germany has now accepted the French and British position it is worth looking at the parameters of scrutiny which domestic regulators will look for when approving products for launch on the market. Dr. David Jeffreys who became the chief executive of the British Medical Device Agency (MDA) on March 1, 2000, outlined the type of evidence required when decisions on market approval and coverage decisions will be made. Among the pieces of evidence they will be looking for are:
• pre-clinical and clinical data
• impact of HTA
• impact of evidence-based medicine/outcome analysis
• availability of guidelines and standards
• depth of guidance
• review of current guidance and standards.

The three countries apply the same criteria for the approval of clinical investigations in submissions for market authorization. Decisions on medical procedures should be based on the best evidence of good practice. They require approval by an ethics committee and informed consent for patient participation in clinical trials. They have legislated mandatory insurance and require notification to the ministry of health. Except for the United Kingdom which requires a 60-day waiting period before a medical device involved in a clinical trial can be used, France and Germany do not require a waiting period (Sorrel 2000).

Although the evidence derived from clinical trials required for regulatory purposes are likely not be as stringent as the evidence required for randomized clinical trials (Lohr et al. 1998), the EU-inspired regulatory process points to the likely ways ahead and shows why the stakes for the industry, clinicians and patients are so high.

In Germany, the Bundesausschuss Ärzte and Krankenkassen has previously rejected industry representation in health technology assessment saying it has a commitment to remain independent in the evaluation process. Now the trade association in Germany, BVMed, argues that its presence would not compromise the committee’s neutrality, as it would settle for an advisory role like the French and British industry have done in the past. From the industry perspective, the best-qualified representative for each individual evaluation procedure should be selected.

In each country, the industry is very concerned about the length of time taken to evaluate a product. For example, Wolfgang Pricken of Novoste GmbH, which manufactures a device for intravascular brachytherapy, elaborated that a surgical procedure with their product only costs DM 5,000 ($2,121) and reduces the potential need for a bypass operation. But it is not included in a DRG, in contrast to a bypass operation included in the reimbursement catalogue and costing between DM 25,000-30,000.

Conclusion. Given the preliminary nature of these findings, further in-depth analysis is needed before final assessments of the effects of European directives and healthcare reforms on domestic decision-making processes can be offered. Despite institutional differences between the three countries, there are common forces at work in each case. However, a major difference between France, Germany and the United Kingdom lies in the degree of central government control over healthcare reform and decisions on domestic implementation, product approval and
reimbursement as well as pricing. Central control has facilitated the consolidation of mechanisms for evaluation and ensuring accountability. By the same token, control over hospital financing, public regulation, public ownership, and public employment in France and the United Kingdom is centralized while the same controls are decentralized in Germany. How the political dynamics play themselves out in a centralized and a decentralized setting is not yet known. However, it is clear that in the German case, regional politics and regional bureaucratic structures within the federation play a key role.

Across the wide array of different cost containment policies, policy approaches between the three countries are fairly similar: more macro- and increasingly micro-management of already heavily regulated delivery sites. Beyond cost containment, in all three countries policy-makers also have embraced a patient-orientation, quality management of hospitals and doctors’ services. Whether this patient-orientation reaches beyond legislative intent and has become a priority mandate in delivery sites is an empirical question that need not be answered here. By contrast and in line with what was said above, although under EU policy all three countries have the same responsibilities and obligations to comply with EU regulatory policy, their approach towards enforcing compliance with EU rules when products are defect, human errors committed or when risks to users and patients are to be avoided. The implementation style in the three countries differs considerably.

Cost containment policies and demands for HTA and EBM over the last decade combine to further tilt the balance of power between the major stakeholders in favor of payers and regulators to the detriment of the medical profession. This process started in the mid-1980s and has accelerated since the 1990s. Medical power over economic issues has been declining over the years. However, the influence and authority status of medical professionals and clinicians as knowledge bearers and technological craftsmen have not declined, although clinical practitioners and office-based physicians are subject to ever increasing restrictive conditions for medical and clinical practice. Neither has the medical profession lost control to police itself according to rules, codes and norms developed by corporatist medicine.

The road ahead is not entirely clear. Four types of uncertainties and restraints lie in the way—one unavoidable, the others unpredictable. The unavoidable one are rising demands for health care, with a rise in the absolute numbers of those over 75 and 80 needing medical care in every healthcare system. The second one is the future role of innovative medical technologies regardless of whether they have a cost-cutting potential or not. The third are the uncertainties surrounding the decision-making behavior of payers and regulators in an atmosphere of tight healthcare budgets and increasing macro- and micro-management. In this atmosphere, the demands for EBM and HTA are unlikely to go away. Finally, it is difficult to predict the future role of the European Court of Justice in raising the question whether national fee schedules and
benefits catalogue are a violation of free trade because corporatist decision-making by German organized medicine and sickness funds is in conflict with European competition policy. If the Court were to rule on this issue against corporatism and price-fixing in national practices, impressive changes can be anticipated long-term.

References


**Endnotes**

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i The concept healthcare reform is used as German politicians used it without attaching a label of incremental or radical policy changes.

ii A number of social court rulings have questioned the conformity of self-regulating rules of sickness funds and organized medicine with EU competition policy.

iii A working group is reported to be evaluating 16 diagnostic and therapeutic procedures and technologies such as:
• percutaneous transluminal coronary angioplasty (PTCA) and stenting in coronary artery disease (including an economic evaluation)
• PTCA and coronary artery bypass graft surgery (CABG) in single and multi vessel coronary artery disease
• Diagnosis of acute sinusitis
• Triple test during pregnancy
• Autologous bone marrow transplantation and high-dose chemotherapy in breast cancer (including economic analysis)
• Preoperative routine diagnostic in elective surgery
• Therapeutic arthroscopy of acute and degenerative disorders of the knee
• Allergen specific immunotherapy (hyposensitization) for acute allergic asthma
• Nuclear resonance imaging in the diagnosis of acute and chronic low back pain
• Surgical interventions in low back pain
• Elective total hip replacement
• Stress echocardiography
• Screening for prostate carcinoma with prostate-specific antigen (PSA) (including an economic evaluation)
• New and established procedures in the treatment of benign prostatic hyperplasia
• Bone density measurement (osteodensitometry)
• Stroke units


• A list of ten procedures was published on 19 October 1999 and included: uterine-balloon cagulation, selective ultraviolet radiation, ionized oxygen insufflation, haematogenous oxidation therapy (HOT) ozone therapy, multi-stage oxygen therapy according to the von Ardenne method and classical homeopathic anamnesis.

iv Kevin Sullivan, Clinica 928, October 2, 2000, p.5.


vi Kevin Sullivan, Clinica October 20, 1999.

vii Kevin Sullivan, Clinica October 20, 1999.


ix Update, Clinica 937 December 4, 2000, p.6.

x The Regulatory Affairs Journal (Devices), August 2000, p.217.


xii Faraz Karmani, Clinica 932, October 2000, pp.1-2.

xiii Kevin Sullivan, Clinica 917, July 17, 2000, p.4.
Standard national accounting in each country provides insufficient data on evidence-based medicine and evidence-based reimbursement. Leading trade journals such as Clinica, Medical Device Technology and The Regulatory Affairs Journal (Devices) give industry perspectives on these issues. Yet this information and much grey-literature published by trade associations, consulting firms and industry representatives is corroborated by the information obtained from interviews in the UK and France.

The TIPS (tarif interministeriel des prestations sanitaires) used to list all products and procedures covered and reimbursed until its dismantling as per June 31, 2000.

Presentation by Dr. Jeffreys at a conference on Medical Device Regulation in London, October 9 and 10, 2000.
EU Policies on the Regulation of Medical Goods and Equipment

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Paper prepared for delivery at the 29th ECPR Joint Workshops, Grenoble, France, April 6-11, 2001. Workshop No. 15 Health Governance in Europe: Europeanization and New Challenges in Health Policies. The paper was presented at the panel RC 25.2 Globalization and European integration: what impact on the social model of medical care? organized by Research Committee 25 Comparative Health Policy, XVIIIth World Congress of the International Political Science Association in Quebec, Canada, on August 1-6, 2000. This paper was written while the author was in residence at MEDIS from April through July, 2000.

Abstract: The regulatory interface between the healthcare industries and governments and between regulators and clinicians over the manufacture, distribution and use of medical products is rapidly changing in all advanced societies. The industries are interested in the elimination of tariff and non-tariff barriers to facilitate international trade, reduce the cost of trading, and gain access to new markets. Medical-scientific circles insist on the availability and accessibility of innovations to clinical researchers and patients who have ever rising expectations about the best treatment. In turn, payers and purchasers of services are concerned about the uncontrolled use of medical technologies without prior assessment of their efficacy and value added in comparison to existing diagnostic and therapeutic capacities. Following the regulation of pharmaceuticals by two decades, the objective of the regulatory regime for medical devices, initiated by the European Union during the 1990s, is to maintain high product quality, safety, and performance standards in integrated European market and beyond. Through focused case studies in France, Germany and the United Kingdom, this paper examines the interface of globalization and the local provision of medical services, focusing in particular on medical vigilance.

Preface:
Global industry and local health care traditions grew out of an interest in European integration and the discovery a few years ago of a dearth of information on the medical device sector. Yet medical devices are used in all facets of clinical practice and patient and home care. They are at the heart of diagnosis, treatment, prevention as well as rehabilitation and are the engine that drives medical progress and innovation. The discovery of a considerable lack of data was surprising at a time when the debate about cost-containment was raging in every single member state of the European Union, on the one hand, and when, on the other, the European Council in its resolution of May 7, 1985, had addressed the concerns of a global industry through new approach legislation to product regulation and the global approach to conformity assessment. Seventeen industrial sectors, including the medical device sector, were affected.

Working through a Global Harmonization Tasks Force (GHTF) since 1993 this industry has promoted regulatory convergence between the leading regulatory regimes: the EU and the US regimes and that of Japan. How well the GHTF is succeeding is a topic of another paper. Clearly, the EU regulatory regime of medical devices follows European regulation of pharmaceuticals and the regulation of medical devices in the United States of America (1976) with a delay of some twenty-five years.

New approach legislation is based on five principles. First, CE-marking serves as a guarantee of conformity to particular regulations. 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 in the pharmaceutical sector, which is subject to old approach legislation. Second, directives, which need to be transposed in their entirety into national law, specify the essential requirements (technical-scientific and clinical) in highly detailed annexe. These must be met as a precondition to obtain market authorization. Third, the annexes make references to harmonized EN or ISO standards (rather than national standards). 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. Finally, and fifth, home country control governs implementation. In other words, member states have considerable discretion in organizing the implementation of these three EU directives.

These ground rules are universal in Europe. They 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. Surprisingly, national policy-makers and researchers still did not perceive, identify or define a need for better information on a variety of topics that would have indicated an awareness that EU regulation on medical devices would generate significant and multiple effects on: the member states, the products, the manufacturers and distributors, purchasers/payers, users and patients as well as the global medical device market. Knowledge and information has been kept by a few insiders to the negotiations in Brussels and, depending on the country, a handful or two of individual officials, scientists and company experts (van Gruting 1994).

The drafters of the EU directives incorporated clinical investigations into the essential requirements: 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.

Yet a search for data in 1996 and again in 1998 (Altenstetter 1996, 1998a) did not identify a single systematic comparative analysis of the distribution and use of medical devices, post-marketing surveillance or medical vigilance. Rather, limited or no information was available on reimbursement and pricing, purchasing practices, site planning of heavy medical equipment, the cost of training of highly skilled staff, equipment utilization, equipment maintenance and servicing (Banta et al. 1994). The transfer of information between investors, clinical investigators and vendors has been a well-kept secret so has been the information on test sites for medical devices and sites funded by medical supplier firms. Information about the conditions under which clinical investigations are performed and incidents or near incidents associated with the use of medical devices examined do not exist in most cases.

If health-policy actors in most EU countries really wanted to know more about these areas, they would turn to implementation research more often than they do. However, the challenges for doing implementation research and analysis are considerable. Implementation research is time-, manpower- and resources-intensive. It is poorly served by academic training programs everywhere–whether at WHO, universities and social science departments, and it has been a stepchild in health policy research. Evaluation research, quantitative analysis and quantitative methods continue to be preferred over qualitative analysis and qualitative research methods.
Field work suggests that enormous changes are under way. There is increasing concern for the quality of medical services and medical vigilance of incidents and accidents associated with the use of medical devices. Awareness is growing everywhere that medical, environmental and food risks to health need to be managed better than they have been in the past. The management of risks to health—perceived and actual—may quite likely become the vehicle for opening up closed channels of information and introducing more transparency. Increased competition and health care reform everywhere combine to move medical supplies, patient-supporting and life-sustaining aids and heavy equipment closer to the center stage of policy-making and health care technology assessment.

In addition, applied research is hampered by the sheer complexity of the sector and the heterogeneity of the products. They range from high ticket items to small ticket items. According to a widely used nomenclature USNMD by ECRI, medical devices include 5,000 different products, 1,400 categories of materials, 2,000 different types of surgical instruments, 450 implants using different materials, over 1 million different marks, models and sizes, and more than 10,000 different manufacturers. This is a mirror-image of the regulatory situation in the European Union.

The industry includes world leaders who dominate the diagnostic product markets (e.g., Baxter and Becton-Dickinson) and Siemens, Hewlett-Packard, Toshiba, Philips and GE-Thompson who dominate the world market in electrical-medical equipment. The major suppliers of implantables are Boston Scientific,... Another feature of the industry is the existence of a large number of small and medium sized firms.

Using medical devices as an entry point to the study of European regulatory integration is an ideal vehicle to explore some of these effects and in particular the effects on national administrative, regulatory and professional practices, and to assess their reach into the health care systems of each member state. It is ideal also for the study of two broader questions. What is the nature and extent of change generated by EU directives? And which of four clusters of factors play a dominant role in bringing change about—EU directives, national regulatory traditions, sector traditions and/or issue characteristics of the sector (Andersen and Eliassen 1995)?

This paper is an integral part of Regulatory regimes in transition: a three country comparison, with a focus on the effects of European integration on the regulatory practices and local healthcare traditions of three member-states. Clearly, European integration is an important driver of change. But this process is subject to the dynamic effects of much broader transformations. For example, EU regulatory integration (as opposed to political and other facets
of integration) is a response to globalization. Attempts to bring about global regulatory convergence is one important aspect of globalization.

Globalization and the sovereignty of nation-states are clearly two important dimensions of change. The dynamics generated by globalization and the defense of sovereign rights impose, though they do not determine, the nature, speed and conditions of change. In health care, the defense of the member states’ exclusive rights over the national health insurance/systems scheme, the organization and practice of medicine is a key issue. Sovereignty over health care is so vital an issue that each time when the Treaty of Rome was amended (the Single European Act of 1985, the Treaty of Maastricht in 1993, and the Treaty of Amsterdam 1997), governments agreed that they would protect their sovereign rights over health care while at the same time adding a new article 152 on public health. The move in two directions need not be considered irreconcilable or mutually exclusive.

The matrix below presents four hypothetical scenarios which speak to the likely interface between global forces and health care. Even under globalization, for most health-related issues, the stage for health politics and policy-making remains quadrant 3 (Nuffield Trust 1999). My research is clearly located in quadrant 3.

| 1) High globalization/low sovereignty assumption: global market forces dominate | 2) Low globalization/low sovereignty assumption: health care is entirely local |
| 3) High globalization/high sovereignty assumption: the complex reality of today | 4) Low globalization/high sovereignty assumption: isolated local health services |

In this context, the objective of this paper is to introduce the theoretical-analytical approach of the research project, its research design, methods and data collection. Next, it provides a brief history of European regulation. Then, it will map the domestic regulatory structure on medical devices, as intended by EU directives, by outlining the new regulatory tasks and tracing the triangular relationship between three major actor groups: the competent authority, the notified body and companies. The paper will conclude with a few comments on what can be expected in the future.

1. Theoretical-analytical framework, research design, methods and data.
This project is an empirical study with a difference. Through the use of primarily
qualitative research methods—interviews, document analysis, and desk research on secondary
literature—this comparison has been specifically designed to give a voice both to central and
local (regional) implementors on the ground in France, Germany and the United Kingdom. Local
and regional implementation of health policy is a fairly under-researched area in each country.

The core issue for this research is: what happens to EU directives after they are
transposed into national law? Blueprints such as the transposed legislative and regulatory texts
specific to medical devices hardly provide the answers. They cannot serve as a basis for saying
something plausible about potential outcomes. Implementation research must go to the source to
find out “the facts” and the “reality” of implementation and to learn what meaning policy actors
give to the implementation of EU directives (Yanow 1996). And as Scharpf (1978:347) wrote
two decades ago “It is unlikely, if not impossible, that public policy of any significance could
result from the choice process of any single unified actor. Policy formation and policy
implementation are inevitably the results of interactions among a plurality of separate actors with
separate interests, goals, and strategies.” This comment is confirmed by many studies and applies
to the implementation of European policy even more so than to national policy implementation.

Regulatory regimes in transition: a three country comparison takes in one sense a
narrower and in another sense a larger approach than other studies on European integration. It is
narrower because this comparison focuses on the medical device sector and the role, decisions
and strategies of a little known and for most people highly invisible yet global industry
(Altenstetter 1994 and 1998b). The topic is reaching deeper because the study attempts to
include the views of regional and local implementing agents, in addition to the mapping of actors
who operate in the macro-foundations of implementation.

A “right” theory of implementation? Quantities of ink have been spilled in the debate
about the “right” theory of implementation and, in particular, between the proponents of a
“bottom-up” or a “top-down” perspective. A similar situation describes the academic debates
about European integration. This paper does not claim to explain cause and effect with regard to
the factors influencing implementation and outcomes. Nor does it discuss the distinction or lack
of distinction between economic or social regulation per se (Majone 1996), or whether regulation
is a distinct type of policy making (Majone 1996 1997; Lowi 1964). The paper is not concerned
with explaining supranational governance (Sandholtz and Stone Sweet 1998), neo-functionalism
or intergovernmentalism. Rather, it focuses on fairly standard questions raised in the literature on
implementation (Najam 1995; Sabatier and Mazmanian 1980; Goggin et al, 1990; Yanow 1996;
Mendrinou 1996).
There is a scholarly consensus in the literature on a broad design, despite heavy disagreements on fine points. Five clusters of factors are hypothesized as shaping though not determining the process of implementation and its final results. These “critical” components are:

• the content of policy before and after EU directives;
• the institutional context (predominantly organizational actors involved in implementation);
• commitment in support of or in opposition to EU regulatory policy;
• capacities (manpower, skills, funds, information and communication); and, finally,
• clients and coalitions (that is, the target groups affected by EU regulatory policy. These are above all: Competent Authorities, notified bodies, manufactures and users.

These influences come into play at every step from transposition of EU directives into national law, implementing decrees, to final results. To implement is to interpret and execute political decisions. Yet it is more than simply translating intentions into decisions and action. It is also about adaptation to national contexts. Putting the pieces of the puzzle between policy intentions and final outcomes together is the ultimate intention of the project.

Evaluation research implicitly accepts the traditional paradigm of public administration while implementation research considers it misleading. Public policy and implementation research prefers to work with the concept policy networks of interacting actors who operate at different levels of decision-making and action. The power of the paradigm in the every day life of policy actors should not be underestimated. It reminds us of strong systemic conditions which shape the cognition, perception and the actions of EU actors and national actors: the existence of a hierarchy of norms and rules, and standard operating procedures (SOPs) which are written with the same logic in mind.

The paradigm is misleading when central actors imply—and they repeatedly do so—that their mandates simply need enforcement in a fairly streamlined implementation process. Yet such rigid control and command mechanisms have never existed in any democracy nor in the 15 EU members. Within their respective constitutional structure, France, Germany and the United Kingdom have placed a premium not only on centralization but also on decentralization. Invariably, central decision-makers have needed to strike a balance between central controls and mandates (EU and national) and the larger political and economic environments. Differences between them are differences in form and degree rather than in fact. The model of public administration is ill-fitted to present a sharp description of the “facts” and “reality” of implementation in any of the three countries. Tracing implementation of EU directives all the way through national, regional and local activities will open a window on national policy adaptations and the underlying causes of inefficient and incomplete implementation and, most
likely, unintended departures from the combined policy intentions of EU and national policy makers.

**Research design, methods and data collection.** The analytical framework mentioned above provided the clues for research design, methodology and data collection. Although track one and two are intertwined, a two-track research design was adopted. Track one: analysis of primary and secondary sources, including grey materials. Track two: observational, interview and process-generated data. A descriptive mapping phase—not yet complete—consists of three sets of activities:

- first, an analysis of published primary EU and member state documents
- second, the development of comprehensive scenarios of implementation
- third, data analysis around a three-dimensional matrix characterizing implementation activities: functions/responsibilities/tasks organizational level (structure, design, control model, authority) the actors of implementation.

Face-to-face interviews with four sets of respondents are planned for all three countries. At the time of writing, about 40 interviews were conducted in the UK and about 100 in France. Because the field work in Germany has not yet begun, this paper cannot address the issue of implementation as seen through the eyes of experienced implementing agents.

**2. Regulating medical devices in the European Union and beyond**

The starting point for this paper on domestic implementation is the general policy on the single market (Art. 100 and 100a) and three medical device-specific directives. *The Council directive on active implantable medical devices (AIMD, 90385/EEC) of June 20, 1990, on the approximation of the laws of the Member States has been in force in the member states since January 1, 1993, and the Council directive on medical devices (MDD, 93/42/42/EEC) since January 1, 1995. The MDD covers all products which are neither implants nor in-vitro diagnostic products. After a delay of more than seven years, *The IVD Directive (98/79/EC) of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic devices was finally published on 7 December 1998 in the Official Journal of the European Communities. Not unexpectedly, the IVD directive of 1998 amended the MDD directive of 1993 in important ways detailed below. The new IVD directive of December 7, 1998, was supposed to come into force on December 7, 1999, but was extended to June 7, 2000 because no member state met the deadline. Variable transition periods for placing on the market apply until 2003, and putting into service until 2005.

**Historical background.** European regulatory policy on medical devices shares a number of characteristics with other sectors. Policy has evolved over time. It is not expressed in one
single EU directive, and it applies to a highly complex and knowledge-based technological sector. The development of a politically and economically acceptable regulatory approach was relatively quick, starting around 1987 when the SEA came into effect and continuing to the present day. Much of the leadership for strategic and operational policy development in this sector came from ministries of health in France, Germany and the United Kingdom, experts from global companies, including U.S. subsidiaries, and European trade associations. How the early promoters of European regulation have written their own preferences into the new regime, how they are altering or reversing the decisions regarding regulatory policy and channels for implementation inherited from the pre-Community regulatory system, and, finally, how EU directives shape the new path in the post-Community system, are among a few intriguing issues for research. But sorting out claims of leadership by one country or countries from facts and actual developments is next to impossible without a step by step review of decision-making on each EU directive. However, there is sufficient evidence to make the case that one country has played a leadership role in the field of diagnostic products, despite political isolation.

The delay of almost eight years in adopting the in vitro diagnostics directive (IVDD) in December 1998 was due in large part to political and strategic differences of opinion between the Commission and the Council and between France, Germany and the United Kingdom. There were also conflicts among the companies in the targeted industrial sector, and there was a widespread resistance to moving away from self-regulation in the IVD product sector toward an EU-imposed regulatory approach. Events beyond the control of the major political forces also left their mark on the first draft (available since 1991). A revised, second draft (1995) became embroiled in the application of the new co-decision procedure between the European Parliament and the Council adopted by the Maastricht Treaty of 1992-1993. The co-decision procedure gave the Parliament a veto right over legislation concerning the single market, health and consumer legislation and the environment. The Amsterdam Treaty extended these rights into other areas. Having placed health issues high on the agenda of the Environment Committee, the European Parliament made full use of its new power by proposing numerous amendments and additions to the draft IVD directive. After several rounds of revisions, the Council and the European Parliament finally agreed on a common position (March 23, 1998) which was revised still further before the final directive was finally adopted in October 1998 and published in December 1998.

In recent years, European parliamentarians from a wide spectrum of political groupings have become increasingly concerned about health and consumer protection issues and health risks arising from unsafe food, including salmonella in eggs and poultry and other issues in the European Union. As a result, European parliamentarians and health advocates share a
widespread perception that the Commission and the Council cannot be trusted to guarantee high standards of health protection in the European Union.

The single most important crisis, which set off intense debate in all political arenas and particularly in the European Parliament, was the BSE scare (Jacob-Creutzfeld disease) and the risks associated with Transmissible Spongiform Encephalopathies. This was of great concern to consumers, health advocates, scientists, and policymakers, as well as farmers, the industry and distributors. After heated debates, national and European policy makers agreed on an EU ban on the use of specific risk materials\textsuperscript{xvi} stemming from bovine, ovine and caprine animals. It has had particular implications for medical devices which uses such materials in their manufacture.\textsuperscript{xvi}

The objective of the ban was to eliminate any risk associated with such materials entering the human and animal food and feed chains.

Today, European regulation of the use of medical devices incorporating human tissue and the use of animal tissues and their derivatives remains unresolved on the European level where the issue has been postponed indefinitely, due to heavy controversy among national governments and in particular among health authorities and regulators from France, Germany and the United Kingdom, as well as disagreements among the industry and the scientific communities. At times, the movement for higher health standards seems to be undercut by a failure of political will among most national governments to act more forcefully. They appear more interested in trade and global competition rather than in human health issues to which they pay lip services. If, however, more public health advocates coalesce around these issues with supportive European and national policy makers, they may develop into a force that will have to be dealt with.

Despite these differences, a heightened health awareness among all European policymakers led to the restructuring of the existing governance structure (formal and informal) of the European Union. This included the addition of a new layer to a highly complex, exceedingly opaque and largely unaccountable multi-level system of governance by committees or what has become known as the “comitology” system of EU governance (van Schendelen 1998).\textsuperscript{xvi} Although scientific advice-giving in EU policy-making has always been available through the Commissions’ advisory, management and regulatory committees, new scientific committees for medical products, medical devices, and veterinary science were established. Consensus among the major stakeholders on the need for scientific advice and new institutional dynamics may combine to mask even more the political-ideological and inter-professional conflicts over these issues than before. The public in most countries, however, still is hesitant to even accept consensus-based scientific evidence.
Feedback of experience. The amendment of the draft IVD directive during 1992 and 1997/1998 offered multiple "opportunities for adaptive policy redefinition" (Elmore 1979) through newly gained experience and information on the pitfalls and strengths of implementing the AIMD and the MDD between 1993 and 1998. This allowed for incorporating stricter national practices into European legislation. For example, article 14(b) provides a legal basis for particular health monitoring measures which some countries are using extensively, such as France and the United Kingdom.

The IVD directive has been a far-reaching driver of change internal to health care. The IVD directive draws a distinction between placing on the market and putting into service:

*Placing on the market* is defined as “the first making available in return for payment or free of charge of a device other than intended for performance evaluation, with a view to distribution and/or use on the Community market”.

*Putting into service* is defined as “the stage at which a device has been available to the final users as being ready for use on the Community market for the first time of its intended purpose.”

Starting June 7, 2000, IVD products can carry the CE-mark with all transition periods ending in 2005. Theoretically, the regulatory regime specific to medical devices will then be completed. However, regulatory integration is a never ending process. It is a process of evolution, learning and adaptation. Thorny issues such as medical standards and clinical investigations, medical waste management, eco-auditing and eco-labeling will have to be resolved eventually.

**France: a special case.** In the process of amending the draft IVD directive in 1997 and 1998, France, along with several prominent scientists and European parliamentarians, wanted to adopt a tougher policy for public health considerations (EUCOMED 1998, 1999). Other EU member states, particularly the UK and Germany but also seven other countries, saw the French plea for public health as an attempt to divert attention from France’s traditional protectionist and state-interventionist position. While the two claims are not without merit, who is to say that France is entirely wrong? Even the supporters of the IVD directive seem unconvinced. A cursory comparison of the first draft of 1990 with the final IVD directive of 1998 suggests that most EU member countries were willing to endorse a higher level of health protection, despite controversies in the Commission, Council and the European Parliament on specific details. For example, despite opposition to a precautionary clause by the UK, Germany and other countries, the EU directive has institutionalized and legitimized the right of a member state to take action on grounds of public health.

Lawyers and others argued that French legislation imposing a three-month pre-market declaration for specific medical products would violate the principle of free trade in medical devices (EUCOMED 1999; McLoughlin 1998; Chignon 1998; Hodges 1999a). But France has begged to differ and has taken the risk of being dragged to the European Court of Justice which
at the time of writing has not yet handed down a ruling. Despite the virulent opposition of practically all other EU member states and the industry, the French parliament adopted a new law to reinforce health surveillance and product safety of all healthcare products designed for human use on June 13, 1998 which became effective on July 1, 1998 (Huriet et Descours 1997, 1998a and 1998b; Girard 1998; Tabuteau 1994, 1996, 1997). One point should be clarified. The debates within France predated the election of the new socialist government in France in September 1997 and have roots in developments internal to France. Spearheaded by a series of dramatic health crises and in particular the scandal on the contaminated blood, hepatitis C, the use of growth hormone, etc. since the mid-1980s French governments of the left and the right have endorsed the same strict position on health surveillance and healthcare product safety.

For a decade now, controversy over the regulation of the use of human or animal tissues and derivatives in medical devices has raged in the Council, the Commission and the European Parliament. The original draft MDD contained a related provision in 1990 but was removed by the Council in 1992. At that time, the use of human tissue was regulated only in Germany under the Drug Law and in France under regulations pertaining to Tissue Banks. France adopted regulation in 1994 and Spain in 1996. The European Parliament also favored stiffer regulations in this area and supported pertinent amendments in March 1996. For the moment, this issue is tabled in the Council. One source close to the European process characterized it as “neither dead nor alive.” Failure to agree on the use of human tissue meant delay and almost derailed the adoption of the IVD directive in 1998. At a meeting in November 1997, the Commission and representatives of other EU countries accepted the majority of French requests. But they did not accept her request for a 60 or 90-day pre-market approval. The adoption of the IVD directive could only be saved by decoupling that issue from the IVD directive in 1998. This provided a solution palatable to all policy makers.

The political and professional communities have been split by controversies over acceptable benefits and risks. They differ on the conduct of clinical investigations and how to document the evaluation of clinical data in order to comply with the relevant requirements for conformity assessment procedures under the new EU regulatory regime (Sorrel 1997; 1998a and 1998b). They disagree on what constitutes acceptable and legitimate clinical data. Are clinical data from experiments in other countries sufficient for market approval (i.e. to obtain the CE mark) or, contrariwise, do clinical experiments need to be carried out in the country in which market approval is sought? Who decides that clinical data are insufficient, and should they be subject to strict requirements of evidence-based medicine? Opinions are strong on both sides of the issues. The divide between strict regulation by the state versus reliance on professional codes
of ethics, and commercial laissez faire versus the pursuit of public health in the interest of the public is deep and real.

In such debates, the influence of a myriad of policy-makers and professions is present in each country. Their influence in the regulatory process stems from their control over administrative procedures and control over three resources: knowledge, expertise and mastery of the necessary techniques and skills. Clinical traditions in Europe’s medical schools, the training, development and application of clinical practice guidelines and health technology assessment differ, despite the universal nature of medicine. On the other hand, all three countries have had entrenched but distinct national industrial practices (Lane 1995). And policy actors have experience with previous interventions and regulatory practices.

**Boundary issues.** To the extent that medical devices and in particular high-risk devices were regulated in France, Germany and the United Kingdom such regulatory requirements were anchored in pharmaceutical drugs regulation. As a result, in negotiating these issues ever since the early 1990, members of different Commission services, business interests and national authorities were pitted against each other. Sometimes, the Commission and company experts were pitted against national authorities. At other times coalitions of actors agreed on the need for European legislation at the high politics and policy level while disagreeing over specific issues. Indeed, coalitions have formed around specific issues and were replaced by other coalitions forming around other issues. For the moment, the thorniest borderline issues between medical devices and medicinal products seem to have been resolved through collective consensus and a shared willingness to address new issues as they arise.

Advances in biotechnology (e.g. tissue engineered skin, bone cement and fillers, cultured cartilage and tissue engineered wound dressings) create new boundary issues. As the former Director-General of the International Association of Prosthesis Manufacturers (IAPM), Victoria Ann Dedrick (1998:566-567), said: "The areas between medicinal products, biologics and medical devices have become significantly grayed in recent years... and "biotechnology offers an unparalleled sweep of new opportunity.” Experts recognize the inadequacy of the existing regimes regulating drugs and medical devices for emerging technologies. But the current safety reporting regulations differ depending on the product--a drug, a biologic, a device or a biological entity. Vigilance systems are based on these distinctions. This procedural diversity presents major challenges to regulatory affairs specialists, company experts and scientists as well as to social science researchers who are interested in learning about the effects of EU directives on administrative processes and the enforcement of national vigilance systems.

**Capacity.** The implementation of the EU directives on medical devices requires a high knowledge-level and highly trained staff. But knowledgeable individuals who understand
regulatory objectives are in short supply everywhere: a handful of civil servants in national departments, regulatory affairs staff in companies, legal specialists in law firms, clinical and dental specialists and sub-specialists as well as experts in laboratory medicine, engineering, materials processing and data specialists. When Competent Authorities need knowledge and expertise which they may not have in-house, they turn to professional and scientific associations of different disciplines and industry experts.

Administrative capacity varies greatly across the fifteen EU member states. In most, it is below capacity, notably the Mediterranean rim and in Central and Eastern Europe. Even staff capacity at the Commission is below capacity with between three and five individuals. With a staff of about 150 individuals at the UK Medical Devices Agency, the United Kingdom has been in a unique position until recently. It has been the only country in the European Union that has had sufficient regulatory manpower capacity and a diversity of professional skills required under one roof (specialists, administrators, medical and nursing staff, professionally qualified technologists and scientists including biologists, chemists, engineers, toxicologists, pharmacists and physicists; and specialists in quality assurance). The single most important factor has been the existence of a centralized NHS structure and considerable experience in voluntary user reporting of incidents and accidents over the last four decades or so. France has shown that she has high ambitions. In 1993 she created the medicinal agency which has become a super-agency, the French agency for healthcare products safety (AFSSAPS) with responsibility over all healthcare products de jure in 1998 but de facto in mid-1999. The government’s own proposals and decisions give a sense of the difficulty of recruiting a balanced mix of needed experts and money. In imitating the FDA it may end up moving closer to the MDA in the United Kingdom.

Despite a collective will to emphasize not only quality, safety and performance but also vigilance and health surveillance, the actual resources made available for this purpose are extremely limited. Neither the Commission nor national governments seem to have authorized more staff or raised the budget for this purpose, with the noticeable exception of France. If the claims that high protection and health safety of patients and consumers are the ultimate goals of the EU regulatory regime are to be credible, rather than exclusively free movement of medical devices across borders, non-discrimination and competitiveness, it is difficult to see how this can be achieved without additional and highly knowledgeable staff and funding.

**Health monitoring.** The two most innovative components of the EU regulatory regime on medical devices is the introduction of post-market surveillance measures and the development of a vigilance system (MDVS), including the acceptance of a safeguard clause, across Europe. PMS fall into the jurisdiction of offices responsible for competition and consumer protection,
which are usually under the jurisdiction of the ministry of economics and industry. The two procedures are independent of each other. As to vigilance, incidents are to be reported within ten days and near incidents within 30 days but France and other countries have adopted more stringent requirements.

“The purpose of the Vigilance system is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent such repetition, or to alleviate the consequences of such incidents.”

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

The Commission’s revised guide (1999, p.99) explains: “The medical devices vigilance systems applies to all incidents which might lead to, or might have led to, the death of a patient or a users, or to a serious deterioration in their state of health, and which result from: any malfunction or deterioration in the characteristics or performance of a device; any inadequacy in the labeling or the instruction for use; or any technical or medical reason in relation to the characteristics or performance of a device, and which leads the manufacturer to systematically recall all devices of the same type.” A new definition was added in the amendments to the IVDD (?).

In the past, at times serious controversies have arisen over the issue of responsibility and liability in the case of accidents or near incidents. On one side, the industry(ies) have claimed that most accidents or incidents are due to the misuse of a medical device by an inexperienced and unskilled user (who could be a physician, a dentist, a technician, a nurse or even a patient using a device at home). On the other side, professionals, public health and consumer advocates, and even scientists and clinicians, say that products are on the market which should not be granted market access and that inappropriate products account for a substantial share of such incidents. For one thing the multiple causes of adverse incidents outlined above do not fit into
easy categories of guilt or no guilt. Published data on reported incidents in France and the United Kingdom, which show an increase of reported incidents over time and a variety of sources which caused an incident or near incident, are challenging manufacturers and diverse professions. When data from Germany and all EU countries are available, ill-founded information may then be replaced by more comparable and reliable rather than anecdotal and partial data. However, due to different clinical and research traditions even then these complex, technological issues may not be translatable into empirical data for easy use.

In theory, a vital tool for post-market surveillance will be the new mandatory European database on medical devices (EUDAMED) accessible to Competent Authorities. EUDAMED will have administrative data bases regarding the registration of manufacturers and devices and distinguishing between (i) placing on the market; (ii) putting into service; (iii) tracking and tracing medical devices in contrast to (iv) tracking and tracing patient-specific devices (patient records); and (v) verification of measuring devices. In practice, once EUDAMED is fully operational, regulators will know the number of certificates issued, modified, suspended, withdrawn or refused. However, overall, progress is slow. Clinical data in the European Union and the member states are handled as personal data and enjoy a high level of protection under the EU Data Protection Directive (95/46/EEC). This can block data transfer to other countries with a lower level of protection, and national legislation.

Who are the driving forces behind this position? Formally, the rights of patients’ and consumers’ are invoked. Informally, in this clue it is difficult to disassociate the interests of patients from those of key economic and professional actors. Some have a keen interest in keeping information under cover for their own interest. Although member states have the jurisdiction to permit processing of health data, they hesitate to upset any political group. Data protection is a complex and politically highly sensitive issue, and each member state has had a distinct history of dealing with data protection issues that cannot be dealt with in this paper.

If available manpower for the operation of a vigilance system and EUDAMED is an indication of what is in store, both will come into use slowly. On the other hand, information on defective products and decisions on alerts, suspensions and withdrawals by regulators in one country is reported to travel fast across all countries in the EEA and to impact upon decision-making by regulators.

Experts agree that the amended MDD has raised the bar for product safety, quality and performance of medical devices under the Medical Devices Vigilance System (MDVS) higher than under general product safety standards (Council Directive 92/59/EEC of 29/6/1992 on General Product Safety). A strict liability regime on manufacturers and importers in the Community was established, although the surveillance of consumer goods is the weaker link in
European policy (Hodges, 1999b). Medical devices must perform according to manufacturers’ claims in their declarations of conformity and scientific literature.

“The performance of a medical device became a legal pre-condition of the CE-mark. As a result the performance of medical device now has to be demonstrated, documented and clinically evaluated and the risk to benefit ratio assessed.” How do medical devices differ from ordinary consumer goods? Hill (1999, pp.3-5) from the German trade association writes that “Medical devices bearing a CE mark according to EC medical device Directive need to be safe and effective (p.3)...Consumer goods only need to be safe. They do not actually have to work.”

For lawyers what counts, above all, are legal documents that can stand up in court. However, consensus-based guidelines of the Commission, the so-called MEDDEVs, are intended to put the vigilance and recall system into action, and they were revised upward rather than downward over the last few years. Even if they have no legal force, they reflect a common understanding of what needs to be done in order to ensure the reporting of incidents and near incidents, the working of vigilance and health monitoring on the ground. MEDDEVs are written by and for all interested parties—device Competent Authorities, Commission services, industries, representatives of healthcare organizations and staff. Each participant in the MEDDEV-writing process represents a stakeholder who through direct participation in one of the many focus groups or working party can influence some aspect of safety, quality and performance of medical devices. And each actor group seems to have drawn some benefit from sharing experience, expertise and knowledge in the past. The European NB-Recommendations (NB-Med), which are prepared by and for Notified Bodies to assist them in developing uniform certification practices across Europe, are now committed to the same goals, as can be seen later. However, note should be taken that the numbering system of NB-MED Recommendations is now in line with the numbering of Commission medical devices guidance documents.

Hodges (1999a) speaks to another feature that is unique to medical devices. And this procedure for conflict resolution was used in the French case. It is the so-called Article 7 Committee chaired by the Commission and which includes the representatives of the member states. The Commission can submit to the committee measures for decision-making. If the committee cannot reach an agreement, the next step will be a decision by the Council. The ultimate step is a procedure before the Court of Justice.

Despite considerable progress of medical device regulation, one weakness remains which will make a difference for the operation of an effective vigilance system in the medical device field. It is the absence of strong traditions in market surveillance in most member states not only in regard to healthcare products and pharmaceuticals but also in regard to consumer goods in general. Hodges (1999b, p.230) quotes the Commission as saying that market
surveillance is “weak, insufficient or ineffective.”...The market is unified but the surveillance is fragmented.” Major implementation problem in medical devices are anticipated. If consumer protection is a weak link in EU regulatory policy, the evidence generated from field work shows glaring gaps in enforcement and monitoring. Who is responsible for the operation of a vigilance system is hardly perceived as a responsibility. Provider awareness of their professional responsibilities under the EU-generated vigilance system is limited as is the monitoring capacity in government offices.

3. EU directives and intended effects on key actors
EU directives have redefined the responsibilities of manufacturers, state-based competent authorities and third party and mostly private certification organizations called notified bodies (NBs). Notified bodies (NBs) are certification organizations appointed by EU member countries to conduct formal audits of products and quality systems. They are primarily private organizations but, as in Germany, they can also include public bodies that accredit NBs to certify and test medical products and inspect manufacturing sites. Irrespective of status, NBs act on behalf of the public authority and work on a contractual basis for a fee.

**Competent Authority.** The IVD directive clarified that, ultimately, Device Competent authorities are politically and legally responsible for oversight, enforcement and compliance (European Commission 1999). The Device Competent Authority are the Healthcare Safety Product Agency (AFSSAPS) in France, the Bundesinstitut für Arzneimittel und Medizinprodukte (BfAMP) in Germany and the Medical Device Agency (MDA) in the United Kingdom. They are at the helm of the implementation process. After consultation with other policy actors they impose central controls and commands on lower-level front-line implementing agents, with variable legal relevance, should a conflict or disagreement end up in court. Who has decision-making authority is matched with clearly defined responsibilities and, more importantly accountability.

They are also asked to step out of their traditional bureaucratic role and stop perceiving their responsibilities under European legislation as merely bureaucratic procedures. They are to step up the reporting of adverse events by users; improve oversight and monitor notified bodies more closely and ensure a more uniform level of certification by Notified Bodies. In the past, lack of oversight and monitoring of NBs by Competent Authorities, and different perceptions and interpretations of their responsibilities are reported as major implementation problems. Clearly, the harmonization of EU rules has not marked the end of national traditions, practices and behaviors.

In other ways, the IVD directive authorizes Competent Authorities to issue health alerts and safety notices when necessary. In the past, most have done so, although with varying degrees
of intensity. Now, they are asked to consult with Notified Bodies in certain cases, and when necessary with the Competent Authority for Medicinal Products for medical devices having an ancillary action (borderline product). The IVD directive widened the possibility for member states to gather information on medical devices in their market regardless of product class.

In addition, Competent Authorities are responsible for all notifications to the Commission, subject to the complex, internal mechanisms for handling European affairs, which differ from country to country. Despite opposition by the industry to multi-language requirements, the new article 14 of the IVD directive empowers the Authorities to request information on labels and instructions for use for higher risk and high risk products such as class IIB and class III devices when these are put into service in their country.

Moreover, national regulators must grant approval of clinical investigations and custom-made devices. For example, a custom-made device is one that is tailored to the needs of a patient by a surgeon. On the basis of reported incidents and near incidents or when a risk to public health exists, they can issue safeguard measures but they must keep regulatory information obtained through vigilance in strict confidence (AIMD 15 and MDD 20). They must provide information to another Competent Authority upon request and do so confidentially. Confidentiality of the identity of the manufacturers does not mean that data on incidents cannot be published. Data on France and the United Kingdom are available. The Commission wants all Authorities to improve the coordination of their activities and transmit information on health and market surveillance more efficiently.

Contrary to the pre-Community regulatory era, Competent Authorities are now responsible for establishing whether a manufacturer followed-up on reported incidents, how this was done, and whether the manufacturer took additional actions suggested by a NB. Competent Authorities are free to engage in as many different oversight functions as they wish. They “may monitor experience with devices of the same kind (for instance, all defibrillators or all syringes), but made by different manufacturers, in order to take measures applicable to all devices of that kind. This could include, for example, initiating user education or suggesting re-classification” (European Commission 1999b).

These guidelines apply to “devices which carry the CE-mark; and devices which do not carry the CE-mark, where such incidents lead to corrective action relevant to CE-marked devices.” Corrective action is defined as a device recall; issue of advisory notice; additional surveillance/modification of devices in use; modification to future device design, components or manufacturing process; modification to labeling or instructions of use.

Hospital administrators, medical practitioners and other health-care professionals, and user representatives responsible for the maintenance and the safety of medical devices, should
take the necessary steps to remedy a problem. Such steps should, where practicable, be taken in co-operation with the manufacturer. In reality, it remains to be seen whether the procedures that trigger a reporting of an adverse incident produce the desired results. To be workable they must have the support of all implementing agents involved—notified bodies, manufacturers, competent authorities and users. The triggering depends on the reporting behavior of users in healthcare delivery sites and individuals who are required under national law to report. Preliminary field information indicates considerable differences in the scope and the responsibilities of individuals between the three countries. In the meantime, Competent Authorities are to improve their oversight over NBs through better cooperation and exchange of experience.

Manufacturers. Manufacturers are responsible for pre-market conformity assessment procedures and the preparation of product documentation for all medical devices, including auditing quality systems in manufacturing sites. They must (i) determine the class of their product, (ii) meet the essential requirements for quality systems and essential requirements in product development, design controls and good laboratory practices; (iii) prepare a Declaration of Conformity, (iv) apply the appropriate conformity assessment scheme, and (v) apply the CE Marking. Obviously, internal document preparation and SOPs have legal implications under liability law, a dimension not pursued here.

For class I devices manufacturers self-declare that their products meet the essential requirements based on the presumption of compliance that harmonized standards are met. No certification by a Notified Body is necessary, except for sterile products and measuring devices which require certification by a Notified Body. For all other classes—class IIa, IIb and III—the involvement of an independent certification body (NB) is required which approves the manufacturer’s declarations that a product meets the essential requirements stipulated in the directives and all related documentation, along with clinical data and scientific literature, supporting this claim. In short, the higher the class the higher the regulatory requirements.

The IVD directive has toughened the requirements for class II (a and b). Manufacturers must meet all notification requirements for new products, and design improvements, and they must have an approval of clinical investigation by a Competent Authority prior to testing. In France, Germany and the UK, as in other EU countries, clinical investigations must be approved by ethics committees and/or professional committees (Sorrel 1997, 1998a and 1998b). Manufacturers must report to the Competent Authority for transfer to the operator of EUDAMED any information on the medical device consultant in their company and his/her qualifications.

Under the vigilance system requires manufactures to report any incident or near incident in the process of manufacturing for recording and evaluation, what they intend to do in response
to an incident and by what date they will provide any requested information. By clarifying that reporting an incident does not constitute “admission of liability for the incident and its consequences” regulators hope to achieve a higher rate of reporting than could be expected without such clarification. For each incident, a final report should be written. Manufacturers must also inform their “authorized representative within the European Economic Area, persons responsible for placing devices on the market and any other agents authorized to act on their behalf. In addition, manufacturers should consider informing official distributors etc. as appropriate during the procedure. But their right to determine a person authorized to be the principle contact point for this purposes is not affected. Finally, manufacturers should inform their NB of those incidents which may affect the certification provided by a particular NB. But the Competent Authority must monitor whether such investigation has been carried out by the manufacturer (European Commission 1999a).

**Third party notification bodies.** New approach legislation in general and regulatory policy on medical devices in particular assign NBs a crucial role in securing—or sometimes not securing, as the critics say—the safety, quality and performance of healthcare products through conformity assessments and CE-marking. CE-marking offers access to the free movement of medical devices on an integrated market within the European Economic Area and soon including countries of Eastern and Central Europe. This integrated market represents about 22 percent of the world market. The US and the EU have signed a mutual recognition agreement. Yet, rather than convergence towards one global regulatory regime on medical devices, there will be approximation between the two most important regimes of the FDA and the European Union. Why only approximation rather than convergence? So far the criticism levied at the EU approach comes from within and outside the EU community and it does center on the role, knowledge capacity and practices of NBs. As long as strong opinions about the superiority of one approach over another exist, there will be regulatory co-existence rather than convergence.

In theory, NBs must be independent, impartial and competent. Independence is defined as having no association with the manufacturer, supplier or installer and being "free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups with an interest in the results of verification." Impartiality of inspection staff must be guaranteed. This is to be achieved by ensuring that “[t]heir remuneration will not depend on the number of controls carried out, nor on the results of such controls." Competency is defined as having qualified staff with special training and all the necessary evaluation and verification experience, the confidential handling of manufacturers’ dossiers, the application of appropriate methods and testing equipment, the
ability to draw up certificates, records and reports to demonstrate that the controls have been
carried out, and carrying of liability insurance.

In practice, accreditation and certification practices by about 61 NBs (up from 40 in 1995) in the European Union are reported to have been liberal and uneven, in the past. Which NBs in which countries are engaging in lax practices and which Competent Authorities do not do their job? These are delicate issues. Even NBs that consider themselves among the best have been implicated in reported incidents with their products as have been world renowned manufacturers. Most EU member states have one or two NBs, while Italy has eight, Norway three, and Sweden three. Of the three country cases included in this study Germany has twenty-five, the United Kingdom six (down from nine) and France one.

The European Diagnostic Manufacturing Association (EDMA) reports that major differences of opinion have existed between the industry and some NBs concerning the risk inherent in IVD products. According to some NBs, the Directive is expected to change the practice of laboratory medicine whereas the industry insist that the IVDD intended to regulate the products only. In the view of some NBs, IVD products are dangerous products and need strict regulation in order to avoid negative outcomes. The industry argues that the products are safe and that past mistakes in the case of HIV were made because users made poor decisions on the use of existing products and failed to use confirmatory tests or made transposition errors.

The IVD directive stiffened the conditions for the designation and surveillance by NBs. “Sufficient scientific staff within the Notified Body shall be available who possess experience and knowledge sufficient to assess the medical functionality and performance of devices having particular regard to essential requirements.” In the interim, even old veterans with a reputation outside Europe have recruited engineers, bio-engineers, physicians and pharmacists. NBs are expected to coordinate their activities and judgments Europe-wide, to improve the exchange of information and experience among each other and between them and the Device Competent Authority.

NBs have been responsive to criticism. Starting in 1997 the representatives of NBs began to meet on a regular basis at the European level in order to standardize requirements for internal procedures, gain necessary expertise and documentation of evaluations carried out by other NBs, and develop recommendations for the collection and presentation of clinical data and guidance documents for the assessment of certain categories of medical devices. By July 1998, five workshops had been conducted on risk analysis and risk management and since then many more. Although attendance is not mandatory, it is reported to be high at about 80% of all European NBs. A British practitioner, Christopher Jepson (1998), spoke to the “reality” of implementation of EU directives:
“Although it is not the role of Notified Bodies (NBs) to enforce the regulations, because of their close relationship with manufacturers in most instances it is the NBs who in practice enforce and implement the MDD. Although in many instances NBs have the sanction of refusing or withdrawing certification, much implementation is undertaken by persuasion.”

They have elaborated European NB-Recommendations, addressing issues of electromagnetic compatibility (EMC). And over the last few years, they have applied stricter rules for enforcing new and significant provisions relating to quality systems, product ranges and clinical investigations, including clinical evaluations. ²

Currently, a Task Force comprised of Commission staff, NBs, and European manufacturers associations is in the process of preparing a recommendation for the evaluation of clinical data in the context of CE marking. It aims to address several outstanding issues: (i) general aspects and conditions of scientific validity of data from scientific literature; (ii) general aspects and conditions of scientific validity of data from clinical investigations; (iii) conditions for the critical report to be provided by the manufacturer; (iv) decision making process including a guidance for addressing the acceptability of the benefit/risk ratios and of the state of the art. Work is also on-going for the assessment of particular categories of high risk devices: devices manufactured with animal tissues or derivatives and breast implants.

Medical devices that have an ancillary action present a special case for implementation. Before making any decisions on these medical devices, notified bodies must consult with the Competent Authority for Medicinal Products. Commission guidelines (MEDDEV.2/12/1) provide clarification on a) the purpose of the consultation procedure, b) the notified body action to initiate a consultation process, c) the documentation to be provided by the Notified Body to the competent authority for medicinal products, and d) the consultation process.

There are also guidelines on a pharmaco-vigilance system. But as for medical devices, medicines regulation may not keep pace with the changing market place and environment. Much scientific work to further harmonize pharmacological regulation is under way at the European level.

The building up of a European regulatory data-base. For the EU regulatory regime to be effective and become successful, a uniform and integrated system of tracking and tracing devices and patients in case of reported injury or defective products is required. In the past, to the extent that accounting was done, this varied greatly among the member states. As previously mentioned, UMDNS developed by the Emergency Care Research Institute (ECRI), USA, is considered workable in the European context and has been adopted as interim standard. European policy-makers adopted it as an interim standard. On the surface, this was a clear case
of face-saving for national governments. Below the surface, most observers agree that a better product classification system may never exist. Informally, this nomenclature is being translated in several countries for internal use and professional use.

For the development of EUDAMED, the European Commission chose the German Institute for Medical Documentation and Information in Cologne (Deutsches Institut für medizinische Dokumentation und Information--DIMDI) from among the bidders. With finances from the Commission, DIMDI produced a workable database within a two-year framework. EUDAMED is reported as having been operational since September 1999 (Hartmann 1999). When regulatory intergration is complete around 2005, all enterprises selling medical products in the European Union, independent of headquarter location in the EU, USA or Japan, will be required to follow the UMDNS nomenclature as adapted to Europe by DIMDI.

DIMDI is accountable to the German federal ministry of health. Under European and German law, it has a number of Europe-wide and German responsibilities: to generate, collect, evaluate and assess data concerning all classes of products, and to provide and transfer data to databanks of member states and EU institutions and EFTA countries, which are signatory parties to the EEA. DIMDI’s new responsibilities include the registration of all notifications on medical devices or design improvements by manufacturers before they are launched on the market. DIMDI keeps track of certificates issued by NBs. Based on information from the Competent Authorities, DIMDI registers all adverse incidents or near incidents (§ 29 MPG, bilingual), all notifications of clinical investigations using medical devices (§17 Abs.6 MPG, bilingual) and general notifications (§ 25 and 31 Abs.4 MPG, bilingual). Moreover, DIMDI makes other data accessible to other public authorities.

**Concluding comments and remedies for the future.** By way of summary, most European countries are asked for the first time to control the access of medical devices to the market and to engage in a post-market and vigilance process in order to ensure the safety of users and patients when using medical devices. The three countries already had some kind of regulatory regime over medical devices--France (statutory), Germany (statutory) and the UK (voluntary) but they put different weight on separate aspects. For example, in France only a small portion of healthcare products were subject to regulation. In Germany, the focus was on the safety of equipment. And the United Kingdom had a voluntary reporting in place for the last forty years or so. For them, the big challenges are now how to overcome the legacy of prior practices and rules, how to apply European legislation and strengthen medical vigilance and incident reporting while maintaining the health protection standards they had achieved prior to the Community-system. The result may be reliance on a complex mix of European and national rules.
The Commission wants to achieve more European uniformity in two ways: by stressing and speeding up standardization even more than in the past and by getting Notified Bodies to develop consensus-based European NB recommendations. To improve levels of protection through standardization, the Commission mandated new standardization work concerning risk management elements and clinical investigation plans.

Most observers consider new approach legislation as applied to medical devices as a considerable progress when compared to what existed before. But some regulators in France, the UK and a few other countries remain concerned about the CE-marking which requires clinical evidence to prove performance but does not require evidence to prove efficacy and effectiveness, unlike standard procedures for market authorization of drugs. Performance is determined by the manufacturer and certified by a notified body. For cultural-political reasons, the notion of a manufacturer’s self-certification is unacceptable to any government of the right and left in France while acceptable to regulators in Germany and the United Kingdom.

What solutions to the criticism of the CE-mark are thinkable? France intends to submit medical devices to evaluation procedures similar to pharmaceuticals to prove efficacy and valued added in comparison to existing diagnoses and therapies by setting higher benefit/risk ratios for new products than has been the case in the past. Most EU regulators agree that the procedures leading to CE marking by strengthening oversight and enforcement over Notified Bodies need improvement. A third solution is to develop stricter EN and ISO standards. A final solution is to use the results of benefit/risk analysis as a basis for decisions on reimbursement based on stringent cost-benefit calculations. Even advocates of rigorous evaluation as a precondition for the CE mark admit, it will bring problems, perhaps even un-solvable ones. The irony is that the industry(ies) and the governments of these three countries have fought hard for building up a regulatory regime for medical devices that would be separate from the regulatory regime for pharmaceuticals, except for border line products, in the past. Now, another layer of “reality” seems to be catching up with the key actors.

One thing seems clear. The Commission is unlikely to look favorably upon member states who intend to act unilaterally. The Commission and, despite an occasional impression that an element of nationalism may be involved, national regulators and politicians for the most part prefer more rather than fewer European rules. And they prefer building bridges between regulators, manufacturers, patients and users and assessors of CE-marking in order to obtain a higher level of safety, quality and performance. From drafting the AIMDD in 1990 and the MDD in 1993 to redrafting the IVDD in 1997-1998, a process of differentiation and toughening has been noticed. European legislation has included ever stricter health protection levels and
more stringent requirements for comprehensive procedures for enforcement. Stricter European rules for high risk products can be expected in the future.

In conclusion, globalization has not led to the erosion of sovereignty over the control of the production, sale, and distribution of safe healthcare products and the safe use of devices in medical practice and patient care any more than has been granted through “high politics” of the member states, the amendments to the Treaty of Rome and the rulings of the European Court of Justice. One may even make the case that globalization, even Europeanization of regulatory requirements, has raised the level of safety for patients and consumers in Europe. However, the control and containment of risks to patients when undergoing medical procedures rests with clinicians, corporately organized professions and hospital managers with different bureaucracies engaged in some kind of oversight.

In addition, Europeanization of regulatory requirements for medical devices, health monitoring and vigilance, by no means, has ended national variations in practices among the member states. Indeed, France, Germany and the UK have retained many high level national regulatory practices which were in place prior to European directives. And they intend to continue to do so in the future.

References


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Endnotes