

A review of the role and responsibilities of national ministries of health in five countries

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Table of contents

Summary	3
Features of Ministries of Health.....	4
Role of the Ministry of Health in relation to collecting funds, budget setting and resource allocation	5
Role of the Ministry of Health in defining the benefits package	7
Role of the Ministry of Health in price setting	8
Role of subordinate agencies.....	10
Role of regional governments.....	11
Summary tables	13
Table 1 Formal allocation of responsibilities and powers in relation to key financing functions: collecting funds	13
Table 2 Formal allocation of responsibilities and powers in relation to key financing functions: budget setting.....	14
Table 3 Allocation of responsibilities and powers in relation to key financing functions: resource allocation.....	15
Table 4 Allocation of responsibilities and powers in relation to key financing functions: defining the benefits package	16
Table 5 Allocation of powers and responsibilities in relation to key financing functions: pricing and reimbursement of pharmaceuticals in the ambulatory sector.....	17
Table 6 Formal allocation of responsibilities and powers in relation to key financing functions: pricing of publicly funded hospital services	18
Country case studies.....	19
1. Denmark.....	20
1.1 Roles and responsibilities	20
1.2 Key governance functions.....	27
1.3 Government scope of action	29
2. France	32
2.1 Roles and responsibilities	32
2.2. Key governance functions.....	39
2.3 Government scope of action	41
3. Germany.....	44
3.1. Roles and responsibilities	44
3.2 Key governance functions.....	52
4. New Zealand	56
4.1 Roles and responsibilities	56
4.2 Key governance functions.....	63
4.3 Government scope of action	65
5. Spain	68
5.1 Roles and responsibilities	68
5.2 Key governance functions.....	74
5.3 Government scope of action	76
References.....	79
Project and contributors	83

Summary

This report reviews the role and responsibilities of ministries of health in five countries: Denmark, France, Germany, New Zealand and Spain. Ministries play an essential role in governing health systems. They are vital in shaping and maintaining the regulatory framework within which health services are funded and delivered. These frameworks, often in the form of national legislation, also define the roles of other health system actors and their responsibility vis-à-vis the Ministry of Health. In addition, ministries are instrumental in developing and implementing government policies and in ensuring that health services are accessible, equitable and affordable.

Ministries vary substantially in size, structure and remit, size of internal departments and the policy areas they oversee. This variation largely reflects differences in mandate but also in the wider political and health system context. The countries selected for this report represent a variety of political systems: traditional federalist (Germany) and quasi-federalist systems (Spain), systems with a high degree of regional responsibility for public services (Denmark) and more centralised countries (France, New Zealand) with contrasting government systems. Federalist and decentralised countries devolve substantial powers to regional and/or local governments, while centralist countries have tended to retain control at the centre. Countries also vary widely with regard to the funding and organisation of health care.

This review has been informed by several key sources: (a) a review of the literature on the role of the ministry of health in health system governance in the countries in question; (b) information provided by country informants in response to a detailed questionnaire; and (c) websites of governments and other organisations identified through (a) and (b). The responses submitted by country informants provided a wealth of information on the organisational structure of ministries, their key responsibilities, mechanisms of accountability, the legislative framework in which they operate and their role in relation to other governmental bodies, arm's length agencies, regional governments and professional and provider organisations. Country informants also provided case studies illustrating ministries' scope of action in cases of health system failure.

The review mainly focuses on the role of ministries of health at the level of central government. It comprises five country case studies and an introduction highlighting some key differences between ministries of health in these countries. The report touches on several topics that are potentially relevant for an understanding of the role and functioning of ministries of health. Topics that may warrant further exploration include: the dynamics within government and, in particular, the relationship between the Ministry of Health and other ministries, such as the Ministry of Finance; the influence of the prime minister, president or equivalent on ministries' activities; the distribution of power within the ministry and the role of different departments; the changing and possibly increasing role of political advisors; the relationship between civil servants and ministry staff with other professional backgrounds; lines and forms of accountability between the ministry, its agencies and regional bodies; and the public perception of a ministry's responsibilities in relation to its actual ability to exercise this responsibility.

Given the limitations of the largely descriptive data available at short notice, this report does not attempt to draw conclusions as to whether some ministries are better able to fulfil their role or better equipped to meet their objectives. Indeed, it is a challenging task simply to describe the allocation of roles and responsibilities of

ministries of health, since frequently there are important if subtle differences between formal definitions and what happens in practice.

Features of Ministries of Health

Ministries vary substantially in size, organisational structure and remit. In Germany, France and New Zealand, ministries are stand-alone government bodies while in Denmark and Spain, the government section responsible for health forms part of a ministry with a broader remit. In Germany responsibility for health was transferred from the previous Ministry of Health and Social Security to the now separate Ministry of Health following the federal election in 2005. The 2007 presidential election in France also resulted in a redistribution of responsibility for health system governance. The social affairs portfolio has been given to a separate ministry and a new Ministry of National Finances, Public Accounts and Civil Services is now responsible for all public spending, including spending on health. In Denmark the Ministry of the Interior and Health oversees the governance of health care exercised through regions and municipalities but is also involved in other aspects of regions' and municipalities' activities. The Ministry of Health at central level in Spain is responsible for health as well as for consumer affairs.

Ministries differ substantially in structure and internal organisation. This largely reflects differences in mandate and responsibilities but may also be related to differences in organisational culture and administrative traditions. Ministries' mandates are shaped by the political system. In countries where regional governments have the main responsibility for organising (and providing) health care, the role of the national ministry of health may be limited to providing the general regulatory framework. In Germany, for example, hospital care is the responsibility of the *Länder* (states); consequently, the federal Ministry of Health's scope of intervention in the hospital sector is limited to selected areas only. Regional governments in Spain appear to be in a similarly strong position vis-à-vis the central Ministry of Health as many functions relating to health system governance have been devolved to the regions. In Germany, the scope of intervention of the federal Ministry of Health is further limited by the strong role of corporatist actors in the health sector. Key functions such as defining the publicly-financed benefits package and price-setting for goods and services are typically carried out by associations of sickness funds and provider associations at central and/or regional level.

Staff numbers also vary among ministries, ranging from 270 at the Danish Ministry of the Interior and Health (of whom only one third work in the health sector) to 1,100 at the Ministry of Health and Consumer Affairs in Spain. However, given the variation in the scope of different ministries' activities and the range of functions discharged by other agencies, it is difficult to draw meaningful conclusions based on the number of staff in a given ministry.

One of the key tasks of any ministry is to provide support to the minister who, in all five countries, is a member of the elected government. Thus, all ministries reviewed here are directly accountable to parliament and, through the minister of health, are answerable to the prime minister (or equivalent) and his/her cabinet. Formal accountability requirements frequently involve reports to parliament on ministry activity and on the performance of the health system. However, approaches and indicators of performance vary widely, as do requirements to make information publicly available. Only in New Zealand is the performance of the Ministry of Health annually measured by parliament against previously stated objectives.

A core function of all ministries of health is to develop the regulatory framework to ensure the functioning of the health system. This typically involves the preparation of health policy legislation to be passed by parliament. In addition, ministries normally issue directives, executive orders and guidelines within the scope of responsibilities assigned to them; these are normally binding for all actors in the health system.

Role of the Ministry of Health in relation to collecting funds, budget setting and resource allocation

In *Denmark* central and local taxes constitute the main mechanism for financing health care. The size of the national budget for health is determined collectively through annual negotiations between the Ministry of Finance, the Ministry of Health, the National Association of Local Authorities and 'Danish Regions' (the representative body of the 98 municipalities and the five regions respectively). The negotiations establish the level of central government subsidies to the regions and municipalities. They also establish the level of redistribution between municipalities to adjust for differences in local tax revenues and the size of one-off or ongoing grants for specific nationally-determined programmes and initiatives. They further set a ceiling on regional and municipal spending on health. The ceiling is not legally binding and municipalities typically respond to budget overspending by raising the level of local taxes.

The outcome of the annual negotiations feeds into the process of determining the central government budget. The Ministry of Finance leads this process. Every year it determines the level of national taxation, which is established by law through the passing of the Finance Act by parliament.¹ It also determines the level of municipal taxes through annual negotiation with the National Association of Local Authorities. Prior to the 2007 administrative reforms, which replaced 14 counties with the five regions, health care was also financed through taxes raised at county level. In contrast, the new regions have no tax-raising powers.

In *France*, management and administration of health care financing largely rests with social security agencies and the health insurance funds. Compulsory contributions are paid by employers and employees and levied on earnings and, since 1991, income. Contribution rates are determined centrally by the government; the actual contributions are collected by local social security offices and pooled nationally.

The role of the central government in health care financing was strengthened following the 1996 Juppé reforms, introducing in 1998 a parliamentary vote to determine an annual maximum ceiling for public spending on health (*L'Objectif nationale de dépenses d'assurance maladie*, ONDAM). Parliament decision is informed by reports prepared by the General Accounting Office, the National Health Conference and by the advice of the Ministry of Health. ONDAM determines a projected budget for health insurance fund expenditure for the following year. If the projected budget is exceeded, a special 'alert' committee, formed in 2004, can ask the national social security agency to present a financial rescue plan. The ceiling also establishes spending limits for specific health sectors (hospital care, ambulatory care and long-term care). Once these spending limits have been set, the Ministry of Health is responsible for allocating funds to each sector and, for hospitals, to each region.² In 2000 a new system required the health insurance funds to sign an agreement with the Ministry of Health specifying a target budget (*Objectif de dépenses déléguées*) for the reimbursement of self-employed health professionals.

However, in 2001 the Ministry and the funds were not able to reach an agreement and the target budget has since been abolished.²

Yet, while central government control over the national health budget has generally increased during the last ten years, the role of the Ministry of Health in administering the health system has been narrowed as responsibility for health care expenditure has been transferred to a new Ministry of National Finances, Public Accounts and Civil Service after the 2007 presidential elections.

In *Germany*, sickness funds play the most important role in the management of health care financing. Contributions paid by employers and employees are levied on earnings and are compulsory for employees earning less than a specified threshold. At present, each sickness fund (currently around 250) sets its own contribution rate and collects the contributions. If expenditures exceed revenues in a given year, sickness funds are required by law to raise their contribution rate. Sickness funds may not incur deficits; they are fully financial liable. However, if a fund runs into severe financial problems, threatening its sustainability, it is to be supported financially by its respective association.³ The sickness funds determine budgets for ambulatory and hospital care in co-operation with the Association of Statutory Health Insurance Physicians (ambulatory care) and the German Hospital Association (hospital care).

Traditionally, the Federal Ministry of Health's role in health care financing has been limited to contribute to developing the overall regulatory framework as part of central government. Its role in health care financing is however likely to increase as it will be responsible for determining a nationally-uniform contribution rate from 2009. This will be based on the analysis of an expert panel to be established by the Federal Insurance Office. The Ministry's decision will take direct effect and will not require approval from the Federal Council, although the government will have to inform parliament. A new national health fund will be established to pool all contributions and to allocate resources in relation to population needs back to the sickness funds. Contributions will continue to be collected by individual sickness funds. The Ministry's influence over health care financing may also increase as the level of tax subsidies paid to the sickness funds rises as a consequence of an earlier reform in 2006.

New Zealand's central government determines the annual budget for publicly-financed health care in the same way as other public services through a process of negotiation involving the Ministry of Health and the Treasury and their respective ministers. The annual budget is approved by parliament. The central government also sets the employer and employee levies that determine the budget of the Accident Compensation Corporation (ACC). The Ministry of Health allocates the government health budget to 21 District Health Boards (DHBs). Within their allocated budget, DHBs fund specific services for their populations, except for services that are purchased by the Ministry of Health (for example, highly specialised services). DHBs have limited discretion in allocating resources as most of their funds are committed in advance to implementing national strategies, ministerial priorities and requirements set out in the Operational Policy Framework.

Health care in *Spain* is mainly financed through taxes raised at central and regional level. In 2001 the central government devolved further tax-raising powers to the regions and the role of the regions in financing health care has subsequently increased.⁴ Central government allocations to the regions for health form part of a broader process of allocation that aims to compensate for differences in tax revenues and needs. Allocations for health and non-health spending are negotiated annually by the central ministry of health, ministry of finance and regional governments.

Regional governments are free to allocate the funds they receive from the central government as they wish, so long as they spend a legally-stipulated minimum amount on health care. Regional ministries of health or their equivalent typically define the overall budget for publicly-financed health care in collaboration with regional ministries of finance and allocate funds by sector.

Role of the Ministry of Health in defining the benefits package

The benefits package has been defined as “the totality of services, activities and goods covered by publicly funded statutory or mandatory insurance schemes or covered and/or provided by national health services” (p. 5).⁵ Busse et al (2005) distinguish higher level decisions, referring to a general framework, frequently defined by legislation, that establishes broad entitlements and lower level decisions, specifying entitlements for specific patient groups and selected applications (e.g. specific technologies and procedures). Lower level specifications that shape the availability and/or reimbursement of services frequently emerge from a combination of legislation passed by parliament, and other legal instruments such as decrees, orders or directives issued by central or regional governments, subordinate agencies or corporatist bodies and other documents and guidelines considered as binding.

In *Denmark* the benefits package is not explicitly defined beyond a broad definition of patient entitlements. In principle, no service is excluded from public reimbursement provided it is clinically indicated: thus treatment decisions are left to the judgement of health professionals.⁶ However, legislation does define selected exclusions and inclusions as well as eligibility criteria and co-payments for specific services. The Ministry of Health has little direct influence on the definition of the benefits package, yet many of its decisions and those of its agencies, notably the National Board of Health and the Danish Medicines Agency, affect patients' access to services for example through policies aiming to control supply and demand (such as general practitioner gatekeeping).

Similarly, in *New Zealand*, the definition of the benefits packages is not explicit. It emerges instead in a complex way from frameworks set by the Ministry of Health through national strategies, an operational policy framework for Districts and policies aimed at specific services and patient groups. The Ministry also maintains so-called 'tool-kits' that describe the features of a 'good' service in major service areas. Within these frameworks, most decisions impacting on the availability of services are made at the regional level by the 21 District Health Boards (DHBs) who act as purchasers of services for their populations. The Ministry's reluctance to define benefits explicitly partly reflects previous experience with unsuccessful attempts to define a minimum benefits package in the 1990s. In particular, attempts by the then Core Services Committee to exclude services from public reimbursement proved to be politically infeasible and were subsequently abandoned.⁷ However, in the pharmaceutical sector the Ministry has a more direct influence on availability through its Pharmaceutical Management Agency, (Pharmac). Pharmac determines the eligibility of pharmaceuticals for public subsidy. It has been a stand-alone agency since 2000. Although Pharmac is directly accountable to the Ministry, it has substantial independence in determining the range of drugs that are publicly financed. The Ministry regularly reviews Pharmac's activities but it rarely intervenes directly or vetoes its decisions.

In *Germany*, the federal Ministry of Health's influence over the benefits package is limited, mainly because related responsibility has been delegated to the Federal Joint

Committee (G-BA). The Committee is the highest federal level decision-making body in the publicly-financed (i.e. statutory) system. Publicly-financed patient entitlements are broadly defined by the Social Code Book. Entitlements are further specified by the Joint Federal Committee, taking into account the positions of other health system stakeholders, including providers and payers. The Committee's decisions have to be submitted to the Ministry for approval and the Ministry may veto a decision within a period of two months.

In *France* the Ministry of Health is equipped with clearly defined authority to veto the decisions of corporatist actors. Responsibility for defining publicly-financed benefits rests with UNCAM (the national union of health insurance schemes, created in 2004). Its decisions are informed by and must take into account advice from two independent bodies: the High Authority on Health (HAS) and the Union of Voluntary Health Insurance (also created in 2004). Unlike in Germany, the Ministry of Health directly participates in the decision-making process, typically represented by its General Directorate for Health. Although the Ministry has the authority to overrule a decision by UNCAM and to add or withdraw services from the benefits package, in practice it has rarely intervened.

The central Ministry of Health in *Spain* has only limited scope for direct intervention in decisions relating to the benefits package. Patients' entitlement to publicly-financed health care is defined by law in the 2003 Cohesion and Quality Act. The Act specifies general entitlements to health care as defined in the Spanish Constitution that have to be provided by the regions. It also identifies areas in which benefits have to be agreed on by the regions, a process co-ordinated by the Interregional Council of the NHS (CISNS). Formed by representatives of each regional government, the CISNS provides a forum for discussion, negotiation and co-ordination of regional health policies, typically involving several tiers of regional government. CISNS decisions usually have the status of recommendations but may also lead to more formal agreements such as the 2006 Royal Decree 1030/2006 which specifies a number of benefits and includes some additions and exclusions. The Ministry of Health participates in the decision-making process, but its role is as a co-ordinator and broker of regional interests rather than a decision maker.

Role of the Ministry of Health in price setting

Decisions on the price of health goods and services influence overall levels of spending on health, with implications for cost control, sustainability and the wider economy. They also affect labour relations through their effect on professional reimbursement and influence the utilisation of health services in terms of the volume of services that can be provided and any patient co-payments required. As a result, prices are of concern to a wide variety of stakeholders, including professional associations, trade unions, pharmaceutical companies and patient organisations.

Pharmaceutical pricing in the ambulatory sector

Pharmaceutical pricing has two main dimensions: determining the price of drugs at different levels of the market chain and determining the level of public reimbursement or subsidy, thereby indirectly determining levels of patient cost sharing. In France and New Zealand, the government exerts some control over the price of pharmaceuticals. In New Zealand, this control is exerted through the Pharmaceutical Management Agency (Pharmac) mentioned earlier. Pharmac is responsible for purchasing pharmaceuticals supplied in the public system and negotiates prices with

suppliers. In France, this takes place through negotiation between the pharmaceutical industry and the inter-ministerial Economic Committee for Medical Products (CEPS).

Actors involved in determining reimbursement levels for pharmaceuticals vary across countries. In Spain, this task is performed by an inter-ministerial committee formed by the Ministry of Health and the Ministry of Finance. In France, the reimbursement level is set by the Commission of Transparency (which, as part of the *Haut Autorité de Santé*, is independent of the Ministry of Health). In Denmark and New Zealand, reimbursement levels are determined by government agencies, the Danish Medicines Agency and Pharmac, respectively. Although both agencies are subordinate to and thus directly accountable to the Ministry, the Ministry typically is not directly involved in decision making. However, the Ministry of Health in New Zealand has the authority to overrule Pharmac's decisions (although in practice it has rarely done so). In Germany, publicly-financed generic drugs are subject to reference pricing. Prices for patented drugs are set by the manufacturer and sickness funds are required to reimburse the full price. For generic drugs, levels of public reimbursement and the clustering of drugs to which a reference price applies are determined by the Federal Joint Committee. As noted above, the Ministry of Health has the right to veto its decisions. In all the countries reviewed here, the extent of patient cost sharing for pharmaceuticals is determined at national level, either through legislation, such as the Danish Health Act or the German Social Code Book V, by an inter-ministerial committee (France) or by the Ministry of Health (New Zealand).

Setting fees for services in ambulatory and hospital care

In most of the countries reviewed here, the ministry of health is not, or not directly, involved in setting prices for services provided in ambulatory and hospital care. *France* might be an exception as the ministry participates in negotiations on fees for the services of general practitioners and office-based specialists between UNCAM (the national union of health insurance schemes) and the professional unions. Agreements require the Ministry's approval.

In Denmark and New Zealand, while not involved in fee-setting negotiations per se the ministry of health provides benchmark prices for hospital reimbursement. In *Denmark*, most provider fees are determined at the regional level. Fees paid to providers of ambulatory care are negotiated between Danish Regions and the respective professional association. Hospital budgets are negotiated between Danish Regions and the individual hospital; these account for 80% of hospital resources. The remaining 20% of the hospital budget is paid through Diagnosis-Related Groups (DRGs). DRG prices are set by the Ministry of Health.

In *New Zealand*, service fees or hospital prices are locally determined through negotiations between District Health Boards (DHBs) and individual provider organisations (i.e. public hospitals or primary health organisations, PHOs). The Ministry provides benchmark prices for hospital services that are used for payment of inter-District patient flows and proposes maximum patient co-payments for primary care services. The latter are not statutorily binding for GPs who are self-employed private practitioners.

In *Germany* and *Spain* the national Ministry of Health is not involved in fee setting in the public sector as negotiations are held at regional level only. In Germany, fees for publicly-financed ambulatory services are determined through negotiation between the regional associations of sickness funds and the regional associations of statutory health insurance physicians. Hospital services are paid through DRGs,

complemented by a number of specific payments to compensate for costs related to activities such as training, research, emergency care and innovative treatment. Prices per DRG are determined for each region through negotiation between the regional association of sickness funds and the regional association of hospitals.⁸

In the Spanish NHS, providers are mainly funded through budgets and capitation. Services are not individually priced. Budgets for public hospitals and capitation fees for ambulatory care are determined by regional ministries of health, typically in co-operation with public provider organisations.

Determining salaries of nurses and doctors

Most national ministries of health tend to not be directly involved in wage determination in the health sector. In France, for example, the salaries of health professionals are typically negotiated between UNCAM (the national union of health insurance schemes) and the unions. However, wage agreements have to be approved by the Ministry. In Denmark and New Zealand salaries are determined through negotiation between professional associations and public payers/employers, usually without participation of the Ministry. In theory, however, the Ministry could intervene if negotiations fail to achieve agreement. Wage negotiations in Germany and Spain mostly take place at the regional level. However, in Spain the Ministry of Public Administration centrally determines a basic salary component for physicians and other health personnel, who enjoy quasi-civil service status.

Role of subordinate agencies

All ministries of health delegate functions to a number of subordinate agencies. These agencies vary substantially in design, structure and size. Subordinate agencies are typically at arm's length from the ministry in the sense that they are separate organisational entities. However, agencies are normally directly accountable to the ministry. Also, the ministry is often held responsible for the performance and decisions of its agencies although it may not be directly involved in their work. Lines of accountability between agencies and the ministry vary among countries.

The number of agencies accountable to the ministry differs substantially across the five countries, as do their tasks and the responsibilities. Some agencies, notably the National Board of Health in Denmark perform a wide array of tasks ranging from monitoring the health system to planning hospital capacity and licensing providers, while other agencies, such as Pharmac in New Zealand, have only been created for a single, albeit important, purpose.

This report does not attempt to provide an exhaustive overview of all agencies involved in health system governance. The following list illustrates the range of responsibilities and tasks delegated to agencies:

- (a) *Monitoring*: Several countries have equipped separate agencies with the task of monitoring population health, such as the National Board of Health in Denmark, the *Institut de veille sanitaire* in France and the Public Health Intelligence Unit in New Zealand. France and Spain have also created bodies to monitor the performance of the health system, the High Council of Public Health in France and the National Health Observatory in Spain. These organisations vary in terms of their degree of separation and independence

from the ministry of health, but are generally designed to provide some assurance that the population health statistics produced are free from political interference.

- (b) *Planning*: Capacity planning is currently delegated to the National Board of Health in Denmark, which is now responsible for approving plans for hospital care for each of the regions. In France, the Agency for Information on Hospital Care (ATIH) collects information on hospital planning, although regional hospital plans are approved by the Ministry of Health.
- (c) *Administrative support to regions*: In several countries, agencies at central level offer technical or advisory support for activities delegated to the regional level. Examples are the Crown Health Financing Agency in New Zealand, which provides financial expertise to regional purchasers (i.e. District Health Boards) and the National Board of Health in Denmark, which runs the nationally uniform system of Diagnosis-Related Groups applied by the regions.
- (d) *Provider licensing/certification*: In Denmark health professionals are licensed and certified by the National Board of Health. In New Zealand, hospital services require certification from HealthCERT, an external business unit of the Ministry of Health. In France, the *Haute Autorité de Santé* (HAS) develops and implements hospital accreditation procedures.
- (e) *Pharmaceutical regulation*: Evaluating pharmaceuticals' safety and efficacy and issuing licences is typically delegated to subordinate government bodies, such as the Danish Medical Agency, the Federal Institute for Pharmaceuticals and Medical Devices in Germany and Medsafe in New Zealand. In France this responsibility rests with the independent *Haute Autorité de Santé*. New Zealand has also established an agency which is involved in pharmaceutical pricing.
- (f) *Patient complaints*: Denmark and New Zealand have created bodies outside the ministry to respond to patients' complaints of poor quality care or professional malpractice (the Patient Complaints Board and the Complaints Board for Patient Injury in Denmark; the Health and Disability Commissioner in New Zealand).
- (g) Other areas delegated to subordinate agencies are typically concerned with: disease control (National Serum Institute in Denmark; Robert Koch Institut in Germany); radiation protection (*Institut de radioprotection et de sûreté nucléaire* in France and the National Radiation Laboratory in New Zealand); food safety (Food Safety Agency in Spain); health education (Federal Centre for Health Education in Germany); coordination and promotion of research (Institute of Health Carlos III, Spain) and the organisation of screening programmes (National Screening Unit, New Zealand).

Role of regional governments

The role of the Ministry of Health at central level is further shaped through the participation of regional governments in health system governance. The role of regional governments varies among countries, broadly mirroring a country's level of political decentralisation. In federal countries such as Germany and Spain, regional

governments have substantial autonomy in organising and managing health care delivery. In Spain, regional governments oversee the entire health system and regulate almost all aspects of health care within their boundaries, except for limited national regulations (such as the core or minimum benefits package). Approaches to organising the health system also vary widely among regions. Regional autonomy has recently been enhanced by devolving further tax-raising powers from the centre to the regions. In Germany *Länder* governments are responsible for ensuring the provision of hospital care and developing legislation and hospital plans to this effect. National legislation does not give the federal Ministry of Health much room for intervention, except in cases that are explicitly defined.

In Germany and Spain arrangements are in place to improve the co-ordination of state/regional policies. In Germany the annual Conference of Health Ministers discusses and co-ordinates regional activities as they relate, mainly, to public health. Meetings are normally attended by the federal Minister of Health or by a representative of the Ministry of Health. In Spain, regional health policies are co-ordinated through the Interregional Council of the NHS (CISNS). This body provides a forum for regional governments and central government organisations. Its role has been strengthened in recent legislation (i.e. through the 2003 Cohesion and Quality Act). Although the central Ministry of Health is represented at the CISNS, it mainly acts as a co-ordinator and facilitator, illustrating the strong position of regional governments.

In Denmark, health care is mainly organised at regional and municipality level and is overseen by elected regional and local councils. Municipalities also raise their own taxes within a framework negotiated with the central government. In France regions (*départements*) have elected governments; however, regional hospital authority board members are essentially representatives of the Ministry of Health and liaise closely with central government organisations. District Health Boards in New Zealand operate within a framework of accountability set by the Ministry of Health and are accountable to the Minister of Health. The Ministry has retained the authority to replace District Health Boards if it finds that their performance is consistently failing.

Summary tables

Table 1 Formal allocation of responsibilities and powers in relation to key financing functions: collecting funds

	<i>Denmark</i>	<i>France</i>	<i>Germany</i>	<i>New Zealand</i>	<i>Spain</i>
Nature of main contribution mechanism (proportion of total expenditure on health)	Central and local (municipal) taxes (84.1%)	Compulsory contributions levied on earnings and income (74.9%)	Compulsory contributions levied on earnings (67.4%)	Central taxes (78.1%)	Central and regional taxes (66.5%)
Main actors	<i>Central taxes:</i> Several ministries led by MoF <i>Municipal taxes:</i> MoF, National Association of Local Authorities	Government, representatives of employees and employers, social security organisations	<i>Contribution rate:</i> Individual sickness funds <i>Risk equalisation scheme:</i> Federal Insurance Office	Parliament, several ministries led by Ministry of Finance	National Council on Financial and Fiscal Policy, national and regional governments
Role of Ministry of Health	Pools central government health budget	n.k.	n.k.	Pools central government health budget	Pools central government health budget
Role of legislature	Approves central and local tax rates (annual Finance Act)	n.k.	Social Code Book V defines role of stakeholders and conditions regarding contribution rates	Parliament approves annual budget	Act 21/2001 specifies taxation responsibilities between centre and regions
Decision-making process	Annual stakeholder negotiations	Annual stakeholder negotiations	Determined at individual fund level	Negotiation between ministries; parliamentary approval	Parliamentary approval ?
Who acts as final arbiter?	Parliament	Government/ Ministry of Health	n.k.	Parliament	Parliament

Source for national expenditure data: OECD Health Data, 2007

Table 2 Formal allocation of responsibilities and powers in relation to key financing functions: budget setting

	<i>Denmark</i>	<i>France</i>	<i>Germany</i>	<i>New Zealand</i>	<i>Spain</i>
<i>Nature of budget</i>	National health care budget	Annual budget ceiling for spending through public health insurance	Provider budgets (ambulatory & hospital care) with legally set limits	Annual budget for health services	Annual budget for health services
<i>Main actors</i>	Ministry of Finance, Ministry of Health, Danish Regions, National Association of Local Authorities	Parliament, new Ministry of National Finances, Public Accounts & Civil Service, 'Alert' Committee, General Accounting Office/National Health Conference (advice)	Associations of sickness funds, association of SHI physicians, German Hospital Association	Ministry of Finance, Ministry of Health	Ministry of Finance, Ministry of Health, regional governments
<i>Role of Ministry of Health</i>	Directly involved in budget negotiations	Advisory	Not involved	Negotiates with MoF	n.k.
<i>Role of legislature</i>	Parliament approves annual budget	Parliament approves budget ceiling	Social Code Book V defines roles of stakeholders	Parliament approves annual budget	Act 21/2001 stipulates minimum health care expenditure level for regions
<i>Decision-making process</i>	Negotiations between stakeholders	Parliamentary vote	Negotiations between stakeholders	Negotiation	n.k.
<i>Who acts as final arbiter?</i>	Parliament	Parliament	n.k.	n.k.	n.k.

Notes:

* Sickness funds in Germany do not have fixed predetermined budgets; they are required to cover all expenses of their insurees.

Table 3 Allocation of responsibilities and powers in relation to key financing functions: resource allocation

	Denmark	France	Germany	New Zealand	Spain
Nature of resources to be allocated	<i>Centre to regions/municipalities</i> : transfer of state subsidies for public services; redistribution of municipality tax income	Division of public funds between sectors, allocation of funds to regions (hospital care), redistribution among health insurance funds	<i>Ambulatory care</i> : regional budgets based on capitation; <i>Hospitals</i> : regional budgets	MoH to DHBs	<i>Centre to regions</i> : allocated based on allocation model; <i>Allocation per sector</i> : varies among regions
Main actors	MOF, MOH, Danish Regions, National Association of Local Authorities	Ministry of Health	Regional sickness funds, regional associations of SHI-physicians, regional hospital associations	Ministry of Health	MOF, MOH, regional governments
Role of Ministry of Health	Allocates central government health budget	Allocates to different sectors / regions (hospitals)	Not involved	Allocates resources to District Health Boards	<i>Centre to regions</i> : Negotiates with regional governments; <i>Allocation per sector</i> : no involvement
Role of legislature	None	None	Roles and rules defined in Social Code Book	None	Rules for regional allocation defined in national legislation (Act 21/2001)
Decision-making process	<i>Centre to regions/municipalities</i> : Negotiations between national ministries and associations of the regions/municipalities	MoH decides allocation per sector within a ceiling set by parliament	Negotiations between regional sickness funds and physician associations (ambulatory); negotiations between sickness funds and hospital associations (hospital)	Ministry of Health decides	<i>Centre to regions</i> : Negotiation between national ministries and regional governments; <i>Allocation per sector</i> : regional governments decide
Who acts as final arbiter?	n.k.	Ministry of Health	n.k.	Ministry of Health	n.k.

Table 4 Allocation of responsibilities and powers in relation to key financing functions: defining the benefits package

	<i>Denmark</i>	<i>France</i>	<i>Germany</i>	<i>New Zealand</i>	<i>Spain</i>
<i>Nature of the benefits package</i>	Not explicitly defined beyond broad legal entitlements	Explicitly defined by positive lists of goods and services	Not explicitly defined beyond broad legal entitlements	Mostly implicit within national priorities	Broadly defined for core benefits to be covered by regional health systems; regional additions possible
<i>Main actors</i>	MoH, National Board of Health, Medicines Agency, Danish Regions, National Association of Local Authorities & provider organisations	National Union of Health Insurance Funds (UNCAM); High Health Authority (advisory), Voluntary Health Insurers Union; MoH	Joint Federal Committee (G-BA), provider organisations, (consultation)	Ministry of Health, Pharmac, (21 District Health Boardss)	Co-ordination of regional additions through Interregional Council of the NHS (CISNS)
<i>Role of Ministry of Health</i>	Minister is empowered by law to issue notices and circulars which are binding to the bodies they are imposed on	May refuse UNCAM's decisions, especially where public health issues are concerned; decisions have to be vetoed within one month	May veto decisions made by G-BA (within a period of 2 months)	Sets objectives & priorities on behalf of Minister of Health; sets operational frameworks, NZGG provides guidelines;	Advice to parliament on core benefits; Participates & co-ordinates negotiations between regional governments within CISNS
<i>Role of legislature</i>	Defines in/exclusions; defines eligibility criteria/co-payments for specific services	The Social Security Code (SSC) defines the range of goods and services reimbursed by the statutory scheme	Social Code Book V defines patient entitlements as they relate to broad service areas funded under the public system	Little direct involvement – package not embodied in legislation	2003 Cohesion & Quality act defines residents' entitlements & specifies areas to be agreed upon by CISNS
<i>Decision-making process</i>	Negotiations, agreements and contracts	Consultation and negotiation	Consultation and negotiation; decisions must be submitted to Ministry of Health	National policy and local purchasers' decisions, but national level predominant	Negotiation and agreement, approved by 2006 Royal Decree
<i>Who acts as final arbiter?</i>	Ministry of Health review and complaints function	Ministry of Health may overrule decision	Ministry of Health may veto G-BA decisions	Ministry of Health	n.k

Table 5 Allocation of powers and responsibilities in relation to key financing functions: pricing and reimbursement of pharmaceuticals in the ambulatory sector

	<i>Denmark</i>	<i>France</i>	<i>Germany</i>	<i>New Zealand</i>	<i>Spain</i>
Nature of 'pricing'	Reimbursement levels; reference pricing	Positive list; reimbursement levels	Reference pricing, pharmacy rebates	Subsidy levels; prices	Reimbursement levels; reference pricing
Main actors	Ministry of Health, Danish Medicines Agency (DMA)	Economic Committee for Medical Products (CEPS), Transparency Commission at HAS (advice), pharmaceutical manufacturers	<i>Reference pricing:</i> Joint Federal Committee, fed. associations of sickness funds <i>Rebates:</i> federal associations of sickness funds; Fed. Association of Pharmacists' Organisations	Pharmaceutical Management Agency (Pharmac)	Interministerial Commission of the Ministry of Health and Ministry of Finance
Role of Ministry of Health	Ministry of Health specifies rules for granting reimbursement (e.g. exemptions, subsidies)	Direct involvement as Member of CEPS; establishes positive of reimbursable drugs per Order	No direct involvement; may veto decisions by G-BA	Indirect through Pharmac as subordinate agency (Board members are appointed by the Minister of Health)	Direct involvement as member if Interministerial Commission
Role of legislature	2007 Health Act defines level of reimbursement of prescription drugs	Ministry of Health Order defines positive list of reimbursable drugs	Social Code Book V defines rules for reference pricing and roles of stakeholders	2000 NZPHDA defines role of Pharmac	1990 Pharmaceuticals Act specifies reimbursement of drugs and price setting; 1993/98 Royal Decrees define exclusions
Decision-making process	<i>Reimbursement levels:</i> regulation (base-rates are defined legally)	<i>Prices:</i> Framework agreements <i>Reimbursement levels:</i> regulation (ministry order)	<i>Reference prices:</i> defined jointly by federal associations of sickness funds	Pharmac Board makes final decision, upon professional/public consultation	Regulation
Who acts as final arbiter?	Law; however, DMA has discretion to overrule on case-by-case basis upon application	Ministry of Health	MoH acts, in consultation with Ministry of Economy, if corporate actors are unable to reach agreement	Pharmac decisions may be vetoed by the Ministry of Health	Ministry of Finance/ Ministry of Health

Table 6 Formal allocation of responsibilities and powers in relation to key financing functions: pricing of publicly funded hospital services

	Denmark	France	Germany	New Zealand	Spain
Nature of 'pricing'	Diagnosis related groups; budgets	Diagnosis related groups; budgets	(regional) Diagnosis related groups; grants	Global budgets; DRGs for inter-district compensation	Global budgets
Main actors	Public hospitals: National Board of Health, Medical Specialties Association Private hospitals: Danish regions, individual hospital	<i>DRGs</i> : Ministry of Health <i>Grants</i> : MoH, Regional Hospital Agencies (ARHs) National Union of Health Insurance Funds (UNCAM)	<i>DRGs</i> : Regional associations of sickness funds & of private health insurers, regional hospital associations <i>Grants</i> : local payers (sickness funds), hospitals	<i>DRGs</i> : determined by association of district health boards (DHBNZ) in co-operation with the Ministry of Health <i>Budgets</i> : DHBs, hospitals	Regional MoHs, regional Health Services Management Organisations (HSMOs), hospitals Private hospitals: regional purchaser (HSMO), private provider associations
Role of Ministry of Health	Determines, through National Board of Health, prices for DRGs (20% of hospital budgets)	<i>DRGs</i> : Ministry of Health updates algorithm and tariffs annually	None - hospital care is the responsibility of the federal states	Ministry of Health defines benchmark prices	None – except that MoH/ government covers deficits incurred by public hospitals
Role of legislature	n.k.	Social Security Code defines roles of stakeholders	Social Code Book V defines the roles of stakeholders	NZPHDA2000 defines roles of stakeholders	n.k.
Decision-making process	Stakeholder negotiations; contracts	Stakeholder negotiations	Stakeholder negotiations; contracts	Stakeholder negotiations; contracts (service agreements)	Stakeholder negotiations
Who acts as final arbiter?	n.k.	Ministry of Health	n.k.	Ministry of Health	n.k.

Country case studies

1. Denmark

1.1 Roles and responsibilities

Legislative framework

The key feature of the Danish health system is its high level of decentralisation, in which regions and municipalities are largely responsible for organising health care. Regions were formed in January 2007 merging the previous 14 counties.¹ The administrative reorganisation involved the partial redistribution of tasks and responsibilities related to the organisation of health care. Tasks relating to supervision of the system were reallocated between the regions, the municipalities and the state.

Responsibilities for health care have most recently been set out in the 2007 Health Act. The act covers all aspects of health care and defines the principles of health care provision in the public sector. These principles include the following:

- easy and equal access to health care services;
- high quality of care;
- co-ordinated services;
- free choice of provider;
- easy access to information;
- transparent health services;
- and short waiting times for care.

The new act consolidates legislation which had previously been spread across a number of different laws. Some specific aspects of health care are also regulated by a number of additional laws relating, for example, to the authorisation of health personnel and the responsibilities of the health professions.

Parliament

The Danish parliament (*Folketing*) legislates on health care. The Minister of Health is responsible for further refining health-related laws, setting rules in certain areas and initiating reforms and bills. Unless it is explicitly established that the Ministry is empowered to amend the law, it can only be changed by the *Folketing*.²

Ministry of Health

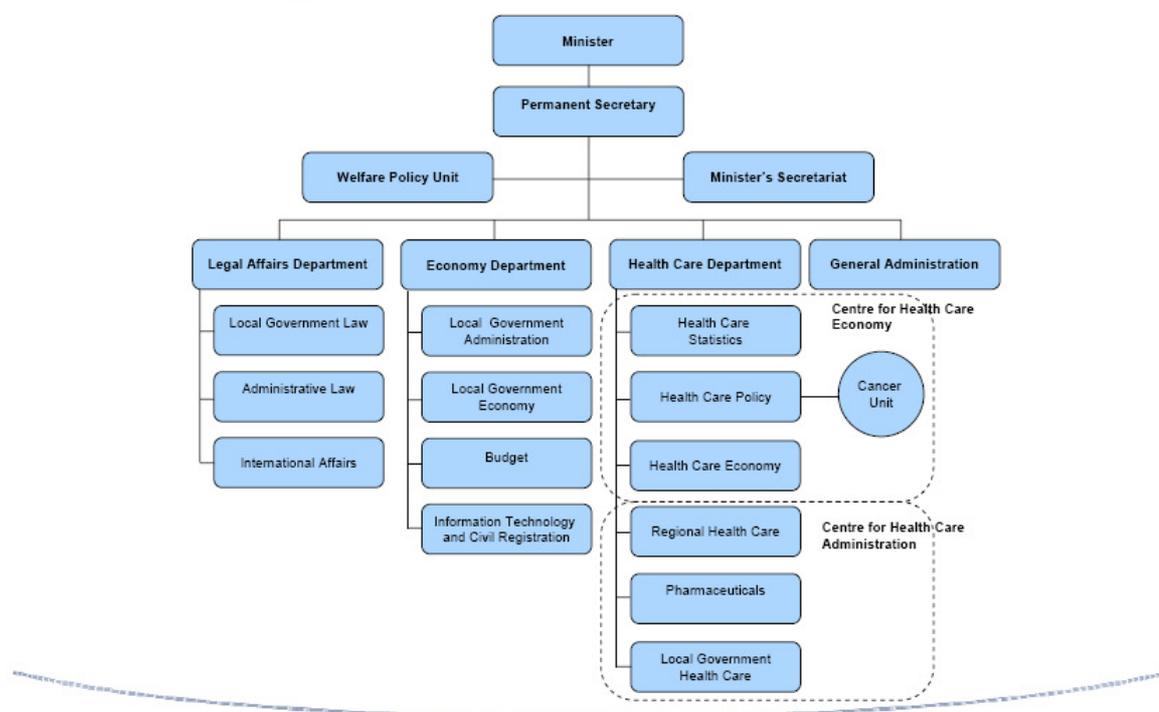
Structure

The Ministry of the Interior and Health was created in 2001 through merger of the Ministry of the Interior and the Ministry of Health. The two ministries had been joined previously but were separated in 1978.^a

The health care department at the Ministry of Health is composed of three departments: the Department of Law; the Department of Finance; and the Department of Health which is further split into the Centre of Health Economics and the Centre of Health Administration (Figure 1.1). The Ministry also has a Secretariat of Welfare Policy, a Ministerial Secretariat and a General Secretariat.

Figure 1.1 Organisation of the Ministry of the Interior and Health³

Ministry of the Interior and Health



Key responsibilities

The Ministry of the Interior and Health is responsible for preparing legislation governing municipal organisation and management, including supervision of municipalities and counties, as well as the financing and economic development of the municipalities. In the field of health, the Ministry provides the overall regulatory framework for the health sector as it relates to organising and financing of health care, including proposing legislation on health provision, personnel, hospitals, the pharmaceutical sector, prevention and health promotion and patients' rights.⁴ Legislation is binding for regions and municipalities. Legislation is typically further

^a Since this case study focuses on the health care-related function of the Ministry, the Ministry will be referred to as Ministry of Health. We will not consider functions related to domestic affairs, which constitute the Ministry's second major remit.

refined by the Ministry through executive orders and guidelines. Executive orders are more binding than guidelines (the latter are often issued by the National Board of Health, the major regulatory agency subordinate to the Ministry of Health; see below).⁴

Each year the Ministry of Health, the Ministry of Finance and the regional and municipal councils—represented by the Danish Regions and the National Association of Local Authorities—take part in a national budget negotiation to set targets for health care expenditure. These targets are not legally binding. However, the central government has the authority to withhold funds, such as grants earmarked for specific purposes, to penalise regions/municipalities if they overrun the budget.

Accountability and performance monitoring

As indicated above, the role of the Ministry of Health is almost exclusively regulatory, supervisory and fiscal. Responsibility for the organisation of health care rests largely with regional and local authorities.⁵

There is no formal system of measuring the performance of the Ministry of Health. However, public scrutiny of issues arising from health service provision is high and the Ministry may be publicly criticised if national legislation is insufficiently implemented (for example in the case of waiting times guarantees, see below). The Ministry is formally accountable to parliament.

The performance of the health system is monitored in part by the National Board of Health.

Health strategy

The Ministry of Health has not published a comprehensive health strategy for the overall health system. However, through the National Board of Health the Ministry has developed a number of strategies for specific areas of care, including a Public Health Strategy (2002), a National Action Plan against Obesity (2004) and a National Cancer Plan (2006). These typically elaborate existing legislation by setting out how a law should be applied in practice.

The Ministry of Health (through the National Board of Health) has also provided additional guidelines for selected procedures (e.g. treatment of life threatening diseases) and has developed a number of strategies that affect the overall health system, including a strategy to promote the use of information technology at local and regional level.

Human resources

The Ministry of the Interior and Health employs 270 staff, one third of whom work directly in the field of health. This number does not include personnel of subordinate agencies, e.g. the National Board of Health

Minister of Health, senior management and political advisors

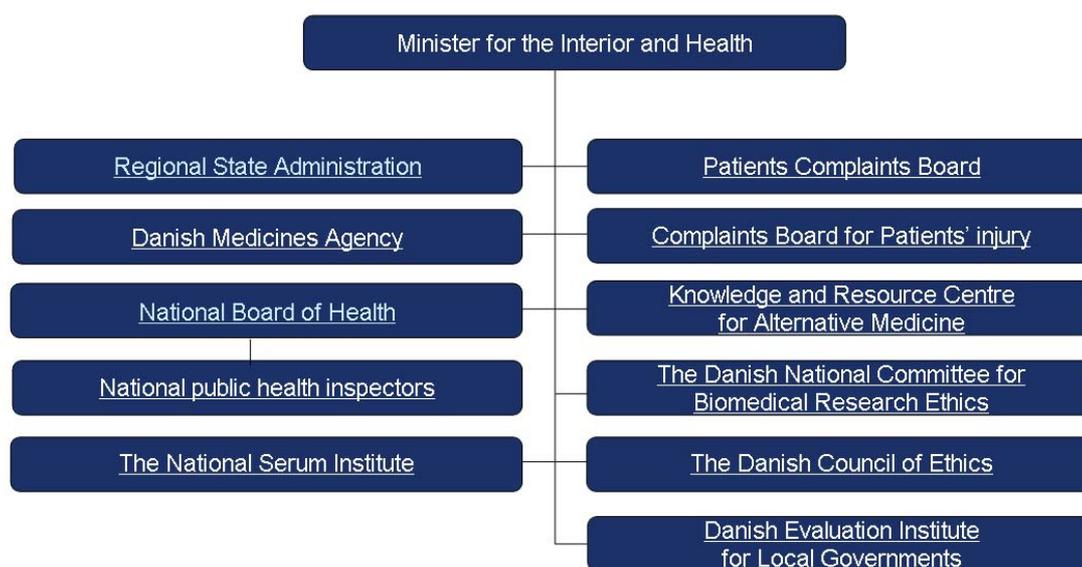
The Minister of Health appoints the Permanent Secretary who appoints most of the other senior executives, including the heads of departments. Choices for these positions are typically not considered to be influenced by party politics, although this may be changing. Traditionally, the posts of senior executives were considered independent from the influence of party politics. However, in the past few years a change of minister has sometimes led to the replacement of the permanent secretary.

Political advisors are typically selected by the Minister based on their expertise and reputation. They usually receive temporary contracts and their term ends with the resignation of the Minister. Their roles may be diverse and some advisors, notably those involved in media/public relations, may be more visible than others. It has been suggested that the influence of advisors has increased in recent years.

Subordinate agencies

The Ministry of Health oversees the activities of a number of subordinate bodies (Figure 1.2).

Figure 1.2 National agencies reporting to the Ministry of Health



The *National Board of Health (Sundhedsstyrelsen)* was established as an independent organisation in 1803 and has since become an agency under the supervision of the Ministry of Health.⁵ It is responsible for supervising health personnel and institutions and for advising different ministries, regions and municipalities on health issues. Its supervisory role was greatly expanded by the 2007 administrative reform.

The role of the Board has been shaped by a number of laws, most of which have now been merged in the 2007 Health Act. Responsibilities were initially defined in the Danish Act on the Central Administration of Health Services and were subsequently

expanded through the Hospitals' Act, the Health Insurance Act, the Physicians' Act, the Act on Certification and Licensing of Health Care Professionals, the Act on the Medical Public Health Officers and the Act of Infectious Diseases.⁶ These roles include:

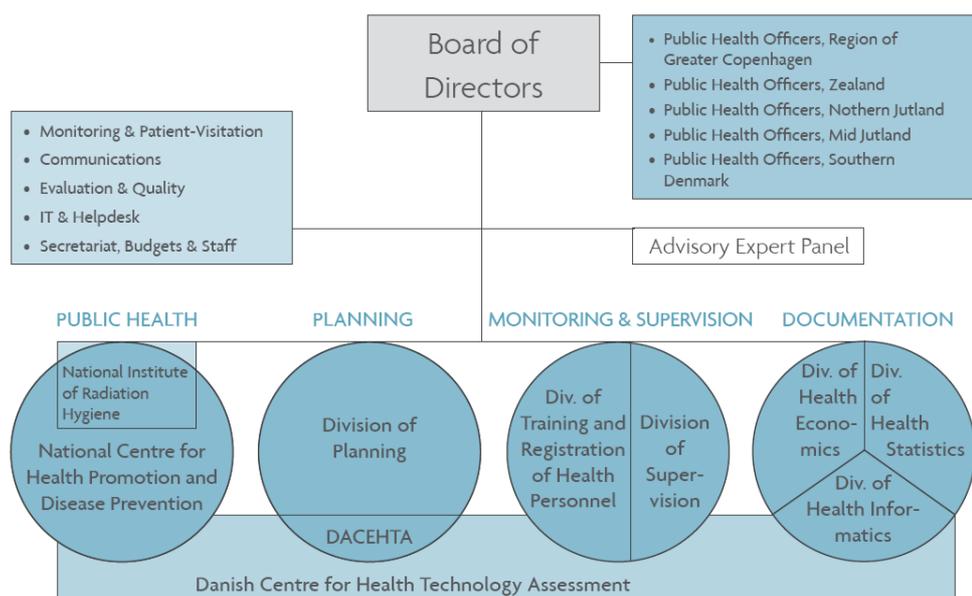
- *Monitoring:* Developing and operating registries, including the National Patient Registry, the Cancer Registry, the Causes of Death Registry and the Health Insurance Service Registry; collection and analysis of statistics on health and health care.
- *Administration:* hospital planning; referral of patients in connection with the Danish treatment guarantee and hospital treatment abroad; developing codes of practice; managing the Danish Diagnosis-related groups (DRG) system; supporting (regional) medical public health officers in developing and managing health care institutions; licensing and certifying of health professionals.
- *Advisory function:* Providing advice to the Ministry and regional and municipal councils on health issues; preparation of reports, instructions and guidelines; responding to questions posed by members of the Danish parliament; issuing of health information to the public (e.g. through information campaigns).
- *Development:* Identifying new treatment and prevention methods; promoting the use of information technology; dissemination of new medical knowledge, development of strategies, health technology assessment and conducting evaluation in the health sector.

In co-operation with the medical societies, the Board also sets standards for quality of care. In 2006, for example, the Board launched an internet-based rating system benchmarking the performance of public hospitals.⁷

The Board's tasks are undertaken by several divisions and centres in four general areas of expertise: Public Health; Planning; Monitoring and Supervision; and Documentation (Figure 1.3). It is led by a Board of Directors (Director-General and three deputy directors) and assisted by an Advisory Expert Panel comprising 22 specialist advisors. Members of the panel are appointed for a period of three years and assist the Board in monitoring developments in over 20 medical specialist areas, midwifery, public health, epidemiology and others.⁶

There are five National Public Health Inspectors (Officers) also attached to the Board. They represent the five regions and are responsible for monitoring health in their respective region.

Figure 1.3 Organisational chart: National Board of Health.³



The *Danish Institute for the Evaluation of Municipalities and Regions (KREVI)* was established in 2005 following the introduction of the Act on the Evaluation of Municipalities and Regions. Its mandate is to analyse and evaluate the performance of municipalities and regions in providing and managing public services (including health care).⁸

More specifically, KREVI has the following key functions:

- *Evaluating public administration:* evaluates and provides comparative analyses of local and regional public administration with the aim of promoting the quality and efficiency of public services and controlling the financial performance of public authorities.
- *Service provision for public authorities:* provides information for the development of strategies to improve the performance of public authorities.
- *Creating a knowledge base:* collects information on international experiences of strategies that enhance public administration performance and develops tools for evaluation, quality improvement and financial control.

The *Danish Medicines Agency* authorises pharmaceuticals and medical devices and products, oversees pharmacies and regulates pharmaceutical reimbursement.

The *Patients' Complaints Board* is responsible for processing patients' complaints as they relate to professional misconduct. It issues warnings to health professionals in case of misconduct and processes serious cases for further consideration by the public prosecutor. The Board does not consider complaints regarding access to treatment.

Other agencies include:

- the *National Serum Institute*⁹
- the *Complaints Board for Patients' Injury* (which handles patients' applications for compensations in case of injuries caused by medical malpractice in the public health system)
- the *Knowledge and Resource Centre for Alternative Medicine (VIFAB)*¹⁰
- the *Danish National Committee for Biomedical Research Ethics*¹¹
- the *Danish Council of Ethics*.¹²

Other Ministries

The *Ministry of Finance* negotiates the level of taxes municipalities are able to raise, thus setting the financial framework for public services (including the provision of health care). The Ministry is also involved in the negotiations of the allocation of public funds from the centre to the regions/municipalities. It also participates in negotiations of professional organisations and unions on salaries, working conditions, fees and the number of practitioners who are allowed to practice within a region (and are contracted by a region).

Regional councils

Denmark's five regions are governed by councils. Councils are elected for four years, comprising 41 members. ^b Unlike the counties, regions do not levy taxes but receive funding from the state and the municipalities; health services and regional development constitute their main tasks. Regions own and run hospitals and prenatal care clinics and fund general practitioners, specialists, physiotherapists, dentists and pharmaceuticals.

At the national level, the regions are jointly represented as the 'Danish Regions'. They are, for example, involved in negotiating salaries for employed health professionals and reimbursements for private practitioners with the different professional organisations. As noted above, negotiations are also attended by the Ministry of Health, the Ministry of Finance and the National Association of Local Authorities.

Regions were only formed in January 2007. At the same time the number of municipalities was reduced from 271 to 98. The 2007 administrative reform has redistributed responsibilities between the national bodies, the regions and the municipalities, involving both centralisation and decentralisation.

Municipalities

Municipalities are governed by councils/boards, elected for four years. In the health sector, their core responsibility is to provide services such as nursing homes, home nursing services, health visitors, municipality dentists, prevention and health promotion services, and facilities for people with special needs. These services are

^b Elections for regional (and municipal) councils can only be held every four years and not in between. Consequently, electoral results tend to be stable throughout each election period, forcing political parties to co-operate rather than to seek political confrontation over controversial topics.

financed through taxation, mainly levied at local level. Municipality boards form sub-committees responsible for specific health or social care services. Municipalities are represented at national level through the National Association of Local Authorities.

1.2 Key governance functions

Definition of the benefits package

The benefits package of health services is not explicitly defined. In principle, no service is excluded as long as it is clinically indicated, i.e. treatment decisions are largely left to the judgement of health professionals.²

Patients' entitlements are only broadly defined through legislation. However, legislation defines selected exclusions and inclusions as well as eligibility criteria or co-payments for specific services. For example, in-vitro fertilisation is restricted to married women under the age of 45 and physiotherapy is only fully reimbursed for certain patient groups, while other groups are required to make a co-payment.²

In practice, access to services is limited by capacity, policies aiming to control supply and demand (e.g. general practitioner gatekeeping) and waiting lists. Decisions made at the level of the Ministry of Health and its agencies, e.g. the National Board of Health and the Danish Medicines Agency, thus substantially shape patients' access to services.

Reimbursement decisions, typically collectively negotiated between service providers (e.g. professional organisations) and all the regions and/or municipalities also affect the availability of services, for example through the authorisation of health professionals or clinical guidelines issued by the National Board of Health.

Overall health care financing

(a) Collection of funds

Central and local taxes constitute the main mechanism for financing health care. Taxes are not earmarked for health, although some are motivated by a concern for health (for example, taxes on tobacco products).⁵ The outcome of annual negotiations involving the Ministry of Finance, the Ministry of Health, Danish Regions and the National Association of Local Authorities (see below) feeds into the process of setting the central government budget. The Ministry of Finance leads this process. Every year it determines the level of national taxation, which is established in law through the passing of the Finance Act by parliament.⁵ It also determines the level of municipal taxes through annual negotiation with the National Association of Local Authorities. Prior to the 2007 administrative reforms, which replaced 14 counties with the five regions, health care was also financed through taxes raised at county level. In contrast, the new regions have no tax-raising powers.

Public finances for health are supplemented by out of pocket payments and private health insurance (14.4% and 1.6% of total expenditure on health respectively). Decisions about the application and level of statutory user charges for prescription drugs and health services are co-ordinated by the Ministry of Health and ratified by parliament through legislation. The level of user charges for dental care is determined by the Ministry of Health based on negotiation with the national dentists' association. Private health insurance covers about a third of the population and

mainly plays a complementary role, reimbursing the cost of statutory user charges and services not covered by the publicly-financed system.

(b) Allocation of funding

The size of the national budget for health is determined collectively, through annual negotiations between the Ministry of Finance, the Ministry of Health, the National Association of Local Authorities and Danish Regions (the representative bodies of the 98 municipalities and the five regions respectively). These negotiations establish the level of central government subsidies to the regions and municipalities. As the regions and municipalities are responsible for different sectors, the process partly determines how much is spent on health care versus social care. The negotiations also establish the level of redistribution between municipalities (to account for differences in local tax revenues) and the size of once-off or ongoing grants for specific nationally-determined programmes and initiatives.

(c) Budget setting

The annual negotiations set a ceiling on regional and municipal spending on health. The ceiling is not legally binding and municipalities typically respond to budget overspending by raising the level of local taxation. However, in the past the central government has penalised overspending municipalities (individually and collectively) by withholding grants.

Price setting

(a) Pharmaceuticals

Pharmaceuticals are not subject to direct price controls but pricing is influenced through the regulation of reimbursement levels. Denmark operates a reference pricing system and since 2005 the reference price for a drug is set at the level of the lowest price paid elsewhere in the European Union. The level of reimbursement of pharmaceuticals is set by the Danish Medicines Agency.

(b) Services in ambulatory and hospital care

Public hospitals are mainly funded through global budgets. They are complemented by payments based on Diagnosis-related groups (DRGs), which constitute 20% of an individual hospital's budget. DRG prices are set by the Ministry of Health. Prices for public services provided in private hospitals are negotiated between the Danish Regions and the individual hospital.

(c) Salaries of nurses and doctors

In the public health sector salaries are negotiated between employers and public payers (i.e. the regional or municipal councils). In public hospitals, nursing homes and municipality health programmes salaries are determined through negotiations between professional organisations, trade unions, the Danish Regions and the National Association of Local Authorities.⁵

Office-based general practitioners receive a mixture of capitation payments (about one third of their income) and fees for services, including special fees for out-of-hours services, telephone consultations and home visits. The level of fees is negotiated between the Association of General Practitioners and the Danish Regions.

Office-based specialists are paid on a fee-for-service basis; fees are negotiated between the respective specialist organisation and the Danish Regions.

Central government is usually not involved in decisions about remuneration. However, if negotiations fail to produce an agreement the government has the authority to intervene for the collective good (e.g. to prevent strikes).

1.3 Government scope of action

In Denmark's decentralised health system responsibility for the functioning of health services is shared between the central government and regional and municipal councils. Decisions about access to specific treatments and pharmaceuticals (e.g. expensive cancer drugs), financial failure of providers and issues of patients safety generally fall under the remit of regions and municipalities and/or are subject to negotiation.

The government, through the Ministry of Health, defines the framework in which health service providers operate. The National Board of Health and other agencies often play a leading role in this process. This framework is determined through legislation (e.g. the Health Act; specific legislation on reporting standards related to patient safety), the development of standards and guidelines, including the licensing (and possible revocation of a licence) of health professionals by the National Board of Health, and specific regulatory functions held by a number of subordinate agencies.

The overall level of direct control the Ministry of Health exerts over the provision of health services appears to be comparatively low. However, it has retained the authority for direct intervention if a specific issue is regarded as politically sensitive. For example, the government has chosen to develop national legislation defining criteria for public reimbursement of in-vitro fertilisation and has set limits on waiting times in response to public demands. However, politically, central intervention comes at a price as central government is likely to be held responsible once a topic is given priority at national level. This dynamic is illustrated by the public controversy surrounding waiting times for cancer patients.

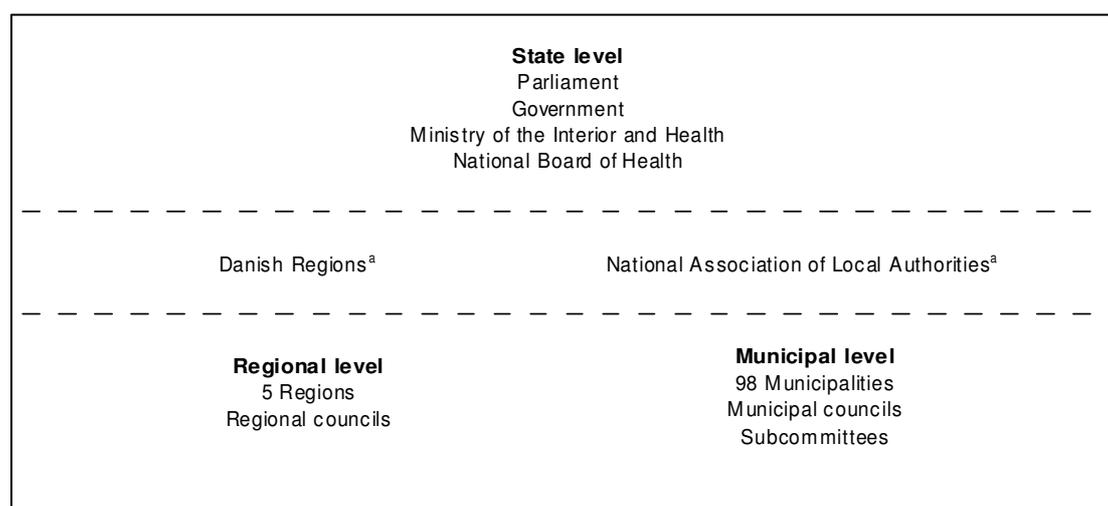
In 2002 the central government introduced legislation establishing a guarantee for patients to be treated at a public hospital within two months of referral or else to be referred to a private facility or to a hospital abroad. For patients with cancer the National Board of Health further specified the guarantee to enhance access to cancer care: waiting times should not exceed two weeks for diagnosis, two weeks for surgery, two weeks for the start of medical treatment and four weeks for radiation treatment. It also specifies that a hospital is responsible for identifying an alternative provider (including private or abroad) if it is unable to treat the patient within the waiting time limit; if the hospital is unable to do so it is required to ask the National Board of Health for assistance.⁵

The implementation of the waiting time guarantee was not straightforward and some hospitals struggled to meet the required standard. In 2006 several newspapers reported cases of cancer patients who had not been treated in time and had not been given the opportunity to be treated elsewhere. The media blamed the Minister of Health for failing to ensure that the waiting time guarantee was evenly implemented and for not keeping the promise to improve access for severely ill patients.

The Ministry of Health in turn criticised the National Board of Health for not assisting the hospital in referring these patients but also for failing to monitor and support the implementation of the policy. The controversy led, eventually, to the resignation of the Board's Chief Medical Officer in November 2006.⁵ The Ministry also criticised hospitals for unduly leaving patients on waiting lists and for failing to organise care in a way that would allow the treatment of cancer patients within the required time frame. Hospitals, in response, argued that they lacked the technical and human resources which would have allowed timely implementation of the waiting time law.

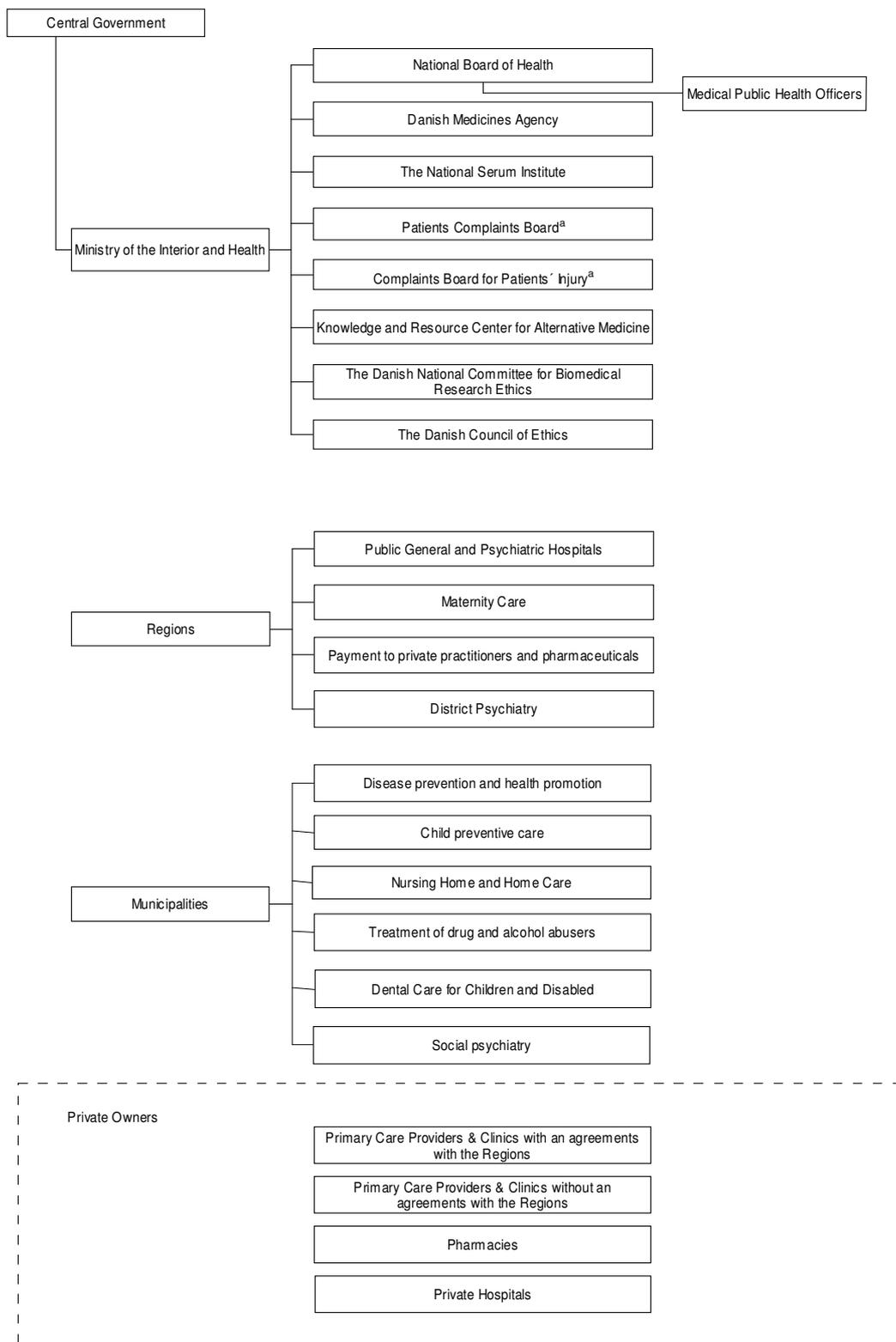
In response to public pressure the Ministry of Health created a special unit, based at the Ministry, to address waiting times for cancer patients. Also, a special task force was formed at the National Board of Health. In addition, the government increased the allocation of funds to the treatment of cancer. However, despite these efforts, access to cancer treatment has remained an issue of public concern. Following another intense public debate in summer 2007 the government and the Danish Regions have announced plans to improve access to cancer care further by reclassifying cancer as an acute disease entitling patients to immediate treatment. An implementation plans is expected to be developed within the next few months. However, representatives of hospitals and of the regions have voiced concern that further improvements to access may be hampered by the lack of technology and available human resources. Some have also warned that the plan may negatively affect access to care for patients with other conditions.

Figure 1.4 Organizational chart of the statutory health system⁵



Note: The Danish Regions and the National Association of Local Authorities are not part of the formal political and administrative system. The associations provide advise to their members and negotiate with professional organizations and the central government.

Figure 1.5 Organisation of the Danish health system⁵



2. France

2.1 Roles and responsibilities

Legislative framework

The basic principles of the French health system were first set out in the ordinance of October 1945, which laid the foundation of the social security system. The specific roles and responsibilities of the actors governing the health system were defined in two subsequent sets of legislation: the public health code (*Code de la santé publique*, 1953) and the social security code (*Code de la sécurité sociale*). The legislative framework has been continuously revised and modified since. The most recent major reform in 2004 introduced through two key documents: the Public Health Act (*Loi de Santé Publique*, 19 January 2004) and the Health Insurance Reform Act (*Loi relative à l'assurance maladie*, 13 August 2004).

The 2004 Public Health Act defines the responsibility of the state in public health (*l'Etat*, which in France is almost synonymous with the central government), which includes, for example, monitoring population health and its determinants; control of infectious diseases; reduction of health inequalities through health promotion and ensuring access to health care and diagnostics across the country; and the quality and safety of health care and health products.¹³

The 2004 act also defines a number of health targets that constitute the framework for the national public health strategy for 2004-2008.¹⁴ The act explicitly states that the government may delegate certain tasks to regional organisations and other health system actors. However, it retains ultimate responsibility for the overall performance of the health system.

The 2004 Health Insurance Reform Act shifted a substantial amount of power from the central government to the sickness funds.¹⁵ It also created several new associations, such as the National Union of Health Insurance Funds (UNCAM) and the National Union of voluntary health insurers (UNOC), incorporating all sickness fund organisations and voluntary health insurers respectively.

The Act strengthened the role of the sickness funds vis-à-vis the state in several ways:

- Sickness funds have a stronger position in negotiating collective agreements with the union of physicians in ambulatory care; the government can veto agreements only on legal grounds or when the health of the public is at risk.
- They have been given responsibility to define the benefits package, to set prices for procedures, devices and pharmaceuticals and to define the level of co-payments. Again, the government's ability to veto decisions is restricted to public health reasons.
- They have been given the capacity and stronger tools to control health care costs and they will do so within a financial framework for three years.¹⁵

Parliament

The French parliament (the General Assembly) plays an important role in regulating the health system. The principles of the system are generally defined through legislation. Regulation often has the status of a law. The parliament has assumed an increasing level of control over the health system following the 1996 'Juppé reforms'.

In 1996, the Act on Social Security Funding (*Loi de financement de la sécurité sociale*) introduced a parliamentary vote to determine an annual maximum ceiling for social health insurance expenditure (known as *Objectif national des dépenses d'assurance maladie, ONDAM*), including spending limits for specific health care sectors. This was executed in 1998 for the first time. The ceiling determined by parliament is based on reports of the General Accounting Office (*Cour des Comptes*) and the National Health Conference which represents all stakeholders including the Regional Hospital Associations. The Act sets a projected target (ceiling) for social health insurance spending for the following year. If the system is found to exceed its projected budget, a special 'alert' committee (see below) can ask the Director of National Health Insurance to present a financial rescue plan.¹⁶

The parliament also approves a report on trends in policy for health and social security and sets out new provisions concerning benefits and regulation. It has also become more strongly involved in reforms and regulatory measures that affect the financial performance of the social health insurance system.

Ministry of Health

Structure

Following the presidential elections of May 2007, the administration of health and social affairs in France was recently spread across three separate ministries: the Ministry of Health, Youth and Sports, the Ministry of Labour, Social Relations and Solidarity and the Ministry of National Finances, Public Accounts and Civil Service. The previous Ministry of Health and Solidarity covered all areas of health and social affairs, whereas under the new structure the Ministry's remit has been narrowed and, through the creation of a separate ministry for national finances (responsible for controlling public expenditure), additional weight has been given to budget control.

The Ministry is divided into several directorates: two departments that are exclusively responsible for health system governance: the General Directorate for Health (DGS) and the Directorate for Hospital Care and Health Organisations (DHOS); and five departments with a broader remit relating to health and social security: the General Directorate for Nuclear Safety and Radiation Protection (DGSNR); General Inspectorate for Health and Social Affairs (IGAS); Directorate of the General Administration, Personnel and Budget (DAGPB); and Information and Communication Group (DICOM).¹⁷

The General Directorate of Health has recently seen major restructuring (Figure 2.1). The Directorate is now divided into seven divisions: legal affairs and ethics; resources; health policy; health services and products; health promotion and chronic disease prevention; prevention of infectious disease; prevention of environment-related and food-borne disease; and a department for health emergencies. The Directorate is also responsible for European and international affairs, scientific support and quality control.

At a local level, the Ministry of Health is represented by its directorates of health and social affairs in the regions (DRASS) and *départements* (DDASS).^c

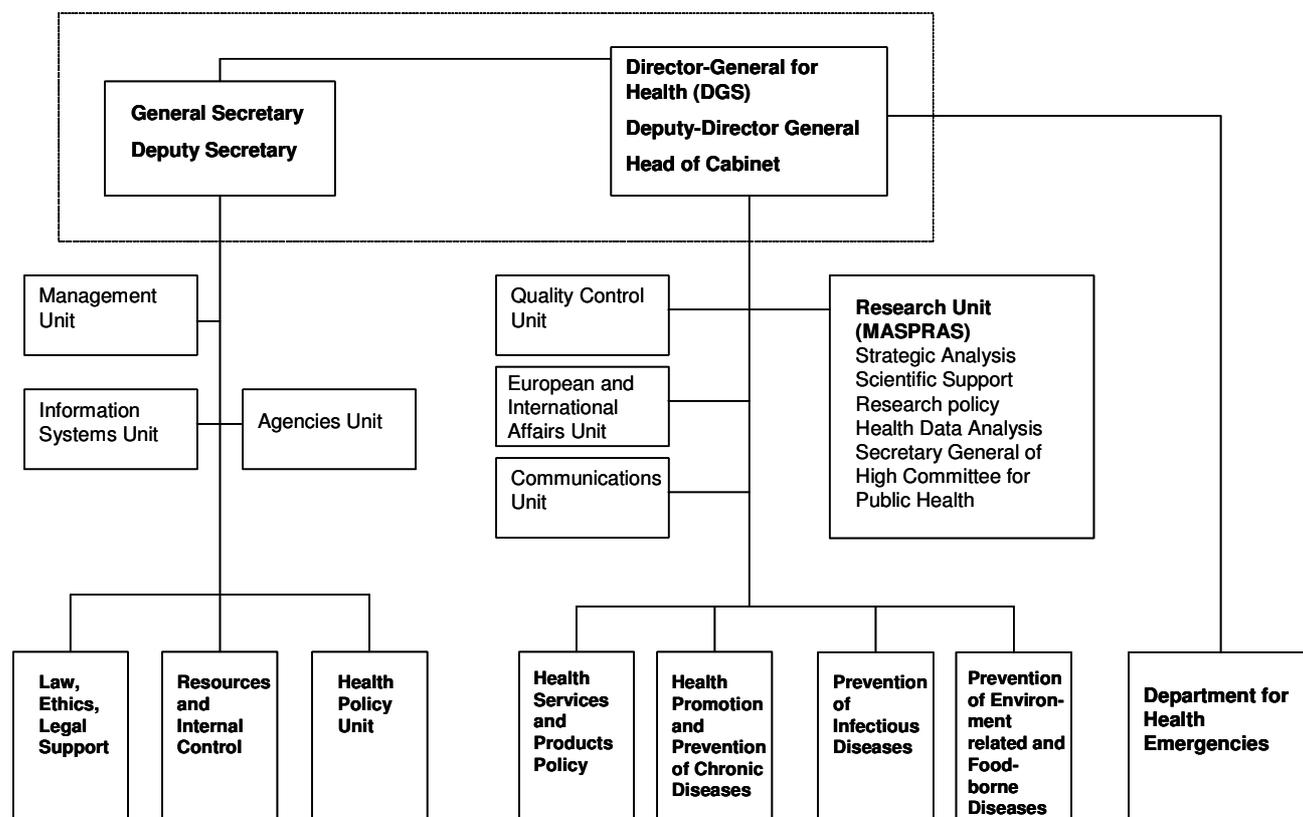


Figure 2.1. Organisational structure of the General Directorate for Health

Key responsibilities

The Ministry of Health is responsible for providing the regulatory framework of the health system, for setting standards and for controlling health care expenditure within a financial framework set by the parliament.¹⁸ More specifically, it

- determines the allocation of budgeted expenditure to different sectors and (where hospitals are concerned) different regions;
- determines the number of medical students to be admitted to medical school each year and approves regional hospital plans;
- approves agreements between the health insurance funds and the unions representing self-employed health care professionals (general practitioners, specialists, dentists, nurses, physiotherapists, midwives and others);

^c France is administratively divided into 100 *départements*, including four overseas. *Départements* are territorial entities with an elected assembly responsible for health and social care and lower secondary education. The 100 *départements* are grouped into 26 regions; these were created in 1955 to provide a structure for regional planning and development.

- approves the prices of specific medical procedures and drugs on the basis of proposals;
- determines safety standards in hospital;
- defines priority areas for national programmes (currently, for example, cancer, pain management and tobacco control).

It is important to note that the scope of responsibilities as listed here is likely to change in the light of the recent reorganisation of the social security administration at the governmental level, in particular as it relates to the financial control responsibilities of the Ministry.

Accountability

As with all public service providers, the Ministry's financial conduct is audited annually by the General Accounting Office (*Cour des Comptes*). Financial performance is also monitored by the parliament, through annual reports to inform the parliament in advance of the annual health care spending debate. There is no formal agreement that defines what the Ministry is expected to produce or deliver.

The annual activity report includes two groups of performance indicators. One group measures the actions taken by the Ministry and the extent to which targets set out in the 2004 Public Health Law have been met.^d For each target, the law specifies the type of data to be produced and the indicators to be used. Indicators for the activity of the Ministry include standard demographic data on the Ministry's employees and the number of laws and bylaws produced. The second set of indicators focuses on the Ministry's internal operations and includes information on spending, recruitment, training and the development of new services such as electronic information services and hotlines. The information provided by the report, including the selection of performance indicators, is relatively broad. Performance measurement is further complicated by frequent reorganisations of the Ministry as responsibilities for health and social security have been redistributed following almost every general election.

Monitoring of the performance and functioning of the health system has been delegated to other public organisations, such as the High Council on Public Health (see below). The Council publishes five-yearly reports on specific public health issues (e.g. nutrition, addiction, violence) and health system issues (e.g. health care financing). These reports have no legal status and recommendations are not binding. However, they have a high profile and receive substantial (media) attention. Health system reports prepared by the Organisation for Economic Co-operation and Development (OECD) and the World Health Organization (WHO) have influenced French health policy by repeatedly pointing out the need for more coordination and efficiency.

Human resources

In 2003, the then Ministry of Social Affairs, Labour and Solidarity that also oversaw health employed approximately 15,000 staff, with 80% working for regional or local authorities. The new Ministry of Health, Youth and Sports employs over 700 people allocated to the two directorates for health (General Directorate for Health: 370; Directorate for Hospital Care and Health Organisations: 340).

^d The 2004 Public Health Law defined 104 health targets, grouped into 22 chapters organised along the broad objectives of the law for the period of 2004-2008.

Minister of Health, senior management and political advisors

The Ministry of Health ranks low in the hierarchy of government organisations. The position of the Minister of Health is considered to be less prestigious than other ministerial posts (such as finance, domestic affairs, justice or foreign affairs) and is usually given to candidates with a lower political profile. However, on occasion the post has been held by high calibre ministers, including Simone Veil (Minister of Health and Social Security 1974-79; President of the European parliament 1979-82; Minister of State, Social Affairs, Health and Cities 1993-95) and Martine Aubry (Minister of Employment and Social Affairs 1997-2000) (the daughter of Jacques Delors). Heads of departments are usually appointed by the President, the Prime Minister or his/her cabinet on the advice of the Minister of Health. The influence of the Minister of Health on nominations depends on his/her political weight.

The Minister of Health is supported by a number of political advisors, who form the Minister's cabinet. The head of the cabinet is usually appointed by the Prime Minister or the Minister of Health (depending on the political weight of the Minister) and based on the candidate's political and administrative experience. The head of the cabinet selects most of the cabinet members, who normally qualify through technical expertise. Advisors have a variety of backgrounds and may bring public or private sector experience. Remuneration is usually based on temporary contracts. Political advisors are seen as bridging politics and administration/civil service. Their role is to initiate and oversee the translation of political intentions into policy.

Political advisors on health may also work for the President or the Prime Minister. They can be extremely influential, sometimes to the extent that they are considered 'shadow health ministers'. It is expected that the advisor on health to the current president Nicolas Sarkozy, Arnold Munich, will be particularly influential.

Subordinate agencies

High Council of Public Health (Haut Conseil de la santé publique)

The Council was established in 2004 by the Public Health Law merging the functions of two previous organisations, the High Level Committee on Public Health (*Haute Comité de santé publique*, established in 1991) and the High Council of Public Hygiene (*Conseil supérieur d'hygiène*, established in 1848). The Council's remit includes: contributing to the setting of health system objectives and assessing whether these objectives have been met; informing responses to health threats and contributing to the design and evaluation of health policies and prevention strategies¹⁹; advising ministries and parliamentary commissions.

Agencies concerned with medical safety, pharmaco-vigilance and warning systems

- *Agence française de sécurité sanitaire des produits de santé (AFSSAPS)*: safety of medical products.
- *Agence française de sécurité sanitaire des aliments (AFSSA)*: regulation of food products.
- *Institut de veille sanitaire (InVS)*: monitoring of population health and public health developments.
- *Institut national de prévention et d'éducation pour la santé (INPES)*: responsible for developing prevention and health promotion strategies (established in 2002).

- *Institut de radioprotection et de sûreté nucléaire (IRNS)*: overseeing radiation safety (established in 2002).

The National Committee on Medical Safety co-ordinates the activities of these organisations.

Economic Committee for Medical Products (CEPS)

The CEPS is an inter-ministerial committee. It sets prices for drugs and medical appliances and monitors trends in spending on drugs in relation to the annual budget targets. It also negotiates agreements with pharmaceutical companies.

Agency for Information on Hospital Care (ATIH)

The ATIH manages the information collected from all hospital stays used for hospital planning and financing.

Other key stakeholders

National Health Conference

A National Health Conference takes place once a year to propose priorities and suggest policy directions to the government and the parliament. The conference brings together representatives from professional organisations, health care institutions and, more recently, patient organisations. Its members also participate in the regular regional health conferences.

Social health insurance funds

The French system of statutory health insurance is divided into three major health insurance schemes: general, agricultural and non-agricultural self-employed. The three schemes cover almost the entire resident population. Membership is broadly defined by type of employment. Each scheme has a national health insurance fund and local structures corresponding to the geographical distribution of the population participating in the scheme. The general scheme, for example, includes 129 local funds to affiliate members and reimburse the cost of treatment; 16 regional funds, which oversee work-related accidents and -illness and related hospital services and prevention; and a national fund for the insurance of salaried employees/employed workers (CNAMTS). CNAMTS supervises the general scheme's regional and local funds; local funds have autonomy of management and separate boards of directors. The national, regional and local boards comprise an equal number of representatives of employers and employees (appointed by the trade unions), between one and three representatives of the mutual insurance associations (providing complementary voluntary (private, non-profit) health insurance) and further representatives appointed by the Minister of Health.

In a major reform in 2004 the three national funds were brought together to form the National Union of Health Insurance Funds (*Union Nationale des Caisses d'Assurance Maladie, UNCAM*). The director-general of this body is also the director of CNAMTS²⁰. S/he has been equipped with stronger executive power at the expense of the board members who, as representatives of employers and employees, had previously been more influential. The director-general:

- is responsible for the operational management of the insurance funds;

- is exclusively responsible for negotiating and signing collective agreements with provider associations/unions;
- nominates the directors of local and regional funds.

The new functions of UNCAM include:

- overseeing the financial governance of the health system (mainly in ambulatory care);
- defining the health care benefits package relating to procedures performed by health care professionals; this process is guided by advice from HAS in consultation UNOCAM (see below);
- regulating prices and tariffs, including determining the level of statutory user charges;
- negotiating collective agreements with doctors in ambulatory care and other professional organisations in private (ambulatory) practice.

Collective agreements require approval from the Ministry of Health. However, approval can only be refused on legal or public health grounds and not, as before the 2004 reform, on the grounds of financial concerns. Thus, the responsibility for cost containment in ambulatory care has to a great extent been shifted from the government to UNCAM.

High Authority for Health (Haute Autorité de santé, HAS)

The High Authority for Health was established in 2004 as an independent scientific public body.²¹ It brings together several functions aiming to improve the quality of health care that were previously held by other organisations, including ANAES.^e HAS

- advises the government and its agencies, the national health insurance funds and other organisations on issues of safety;
- develops safety standards and assesses drugs, medical devices and procedures;
- develops and implements hospital accreditation procedures;
- develops and disseminates clinical practice guidelines and evaluates professional practice of physicians.

HAS acts in support of all health system stakeholders including the Parliament, the Ministry of Health, the health insurance funds, the medical associations and patient organisations.

'Alert' Committee

The 'Alert' committee (*Comité d'alerte sur l'évolution des dépenses d'assurance maladie*) was created in 2004 and is composed of the secretary general of the Social Security Accounting Commission (*Commission des comptes de la sécurité sociale*), the director general of the National Institute for Statistics and an additional expert appointed by the president of the Economic and Social Council. The role of the committee is to monitor the expenditure of sickness funds and to 'alert' the sickness funds if they exceed the legally determined spending ceiling.

^e ANAES (Agency for Accreditation and Evaluation of Health Care, *Agence Nationale d'Accréditation et Evaluation en Santé*) was established in 1997 following the 1996 'Juppé reform'.

Regional hospital agencies (ARH)

Regional hospital agencies (ARH) are responsible for planning hospital care (private and public hospitals), resource allocation to public hospitals and adjusting tariffs for private for-profit hospitals. These tasks are undertaken within the framework of national agreements. ARH bring together, at the regional level, the health services of the state and the health insurance funds, which previously shared management of the hospital sector. ARH directors are appointed by the Cabinet of Ministers and are directly accountable to the Minister of Health.

There are currently plans under discussion to transform ARH into regional health authorities and to expand their remit to ambulatory care, long-term care and public health.

Regional public health groups

Set up in 2004, regional public health groups (*Groupements régionaux de santé publique*, GRSP) bring together the representatives of the state and national agencies that are involved in public health policies at the regional level, including the ARH, the health insurance funds and the local authorities (if these choose to be involved). The GRSP plan services and actions as they relate to public health within the framework set by regional health conferences (see below).

Regional health conferences

Regional conferences bring together regional actors (provider, professional and patient organisations). They assess regional health needs, set regional priorities within the framework of the national health targets and suggest a regional public health plan. The plan is typically approved by the regional representative of the state (*préfet*). The conference also assesses the performance of the GRSP against set targets.

Other stakeholders at the regional level

- *Regional unions of the health insurance funds (URCAM)*: co-ordinate the work of the three major social health insurance schemes at the regional level; they do not have decision-making power over regional or local funds.
- *Regional unions of self-employed doctors (URML)*: have an advisory role with regard to the functioning of the health system, especially as far as private medical practice is concerned; they are engaged in dialogue with the ARH and the URCAM.

2.2. Key governance functions

Defining the benefits package

The benefits package of services reimbursed through the social health insurance system is defined by UNCAM, the National Union of Health Insurance Funds set up in 2004. As mentioned before, this process is guided by advice from the HAS. The Union of Voluntary Health Insurers (*Union Nationale des Organismes Complémentaires d'Assurance Maladie*, UNOCAM), also set up in 2004, is involved through consultation.

The Ministry of Health participates in the process of defining benefits through consultation. It is typically represented by the General Directorate for Health. The Ministry has the authority to overrule a decision and to add or withdraw services from the publicly funded package. These interventions are, however, rare; they have mainly occurred in response to emergency situations.

A basic benefits package was recently defined for patients with chronic illnesses who are eligible for the full reimbursement of their health care costs through social insurance. Decisions on services to be included are delegated to UNCAM; decisions are informed by HAS. This illustrates the level of power UNCAM now has in matters of financial impact.

Overall health care financing

(a) Collection of funds

Compulsory contributions are paid by employers and employees and levied on earnings and income. In 2000 the *Couverture maladie universelle* (CMU) Act changed the basis for entitlement to national health insurance from occupational status (i.e. being employed) to being resident in France. Contribution rates are set centrally by the Ministry of Finance. Contributions for health and other aspects of social security are collected by local social security offices, pooled by the national office and passed on to the health insurance funds.

In 2005 out of pocket payments accounted for 7.4% and private health insurance for 12.8% of total expenditure on health respectively.²² The level of health care costs reimbursed by the publicly-financed health system is determined by the Ministry of Health. Changes to these levels are proposed by the health insurance funds but must be approved by the Ministry of Health.¹⁸ Private health insurance mainly covers the cost of statutory user charges and is predominantly provided by mutual associations governed by the *Code de la Mutualité*.

Allocation of funds and budget setting

The Juppé reforms of 1996 strengthened the role of the central government in health care financing, particularly through the introduction in 1998 of a parliamentary vote to determine an annual maximum ceiling for public spending on health (*L'Objectif nationale de dépenses d'assurance maladie*, ONDAM). Parliament bases its decision on reports prepared by the General Accounting Office (*Cour des Comptes*) and the National Health Conference^f. ONDAM sets a projected budget for health insurance fund expenditure for the following year. If the projected budget is exceeded, a special 'alert' committee (see above) formed in 2004 can ask the national social security agency (*Sécurité Sociale*) to present a financial rescue plan. The ceiling also establishes spending limits for specific health sectors (hospital care, ambulatory care and long-term care). Once these spending limits have been set, the Ministry of Health is responsible for allocating funds to each sector and, for hospitals, to each region.¹⁸

^f The National Health Conference represents all non-governmental stakeholders.

Price setting

(a) Pharmaceuticals

Pharmaceuticals have to be included in a positive list to qualify for reimbursement through social health insurance.⁹ The positive list is overseen by the Ministry of Health. Decisions to include or exclude specific drugs are taken on the advice of the Commission on Transparency. Pricing decisions are made by the Economic Committee for Medical Products (CEPS). The Commission is part of HAS (i.e. independent from the Ministry).¹⁸

These bodies also define levels of reimbursement by classifying the effect of a drug (and other medical services) as 'major/considerable' (reimbursed 65%), 'moderate' (35%), 'low but reimbursable' (35%) or 'insufficient' (0%).

(b) Health services in ambulatory and hospital care

Prices for services provided in ambulatory care and in hospital (Diagnosis-related groups and additional grants) are set by UNCAM following negotiations with the Ministry of Health and the unions. The Ministry of National Finances, Public Accounts and Civil Service is not yet involved in these negotiations.

(c) Salaries for nurses and doctors

Salaries of hospital doctors and nurses are determined by UNCAM following negotiations with the Ministry of Health and the unions. Office-based general practitioners and specialists are self-employed and are reimbursed on a fee-for-service basis. Prices for these services are determined through agreements between UNCAM, the Ministry of Health and the respective professional union.

2.3 Government scope of action

The Ministry of Health has considerable control over the health system. This is despite recent attempts to decentralise aspects of governance through responsibility from central to regional authorities (e.g. hospital planning) and from national agencies to independent organisations (HAS replacing ANAES). In all major areas the Ministry is either directly involved in decision-making or it has retained the authority to overrule a decision made elsewhere.

The Ministry can influence decisions concerning public funding of life-saving drugs and in-vitro fertilisation. It also approves regional hospital plans and has a final say in matters of hospital restructuring and closure of hospitals and hospital departments. Although most decisions about major financial investments are now taken at the regional level, the Ministry is involved in many of these decisions.

The Ministry can also take direct action in response to concerns about patient safety. Issues such as hospital-acquired infections are expected to be investigated by HAS and reported to regional health authorities. In serious cases, the local representative of the state (i.e. the prefect of the *département*) has the authority to close a hospital. The Ministry may also commission reviews of the performance of a provider organisation or an agency. Performance reviews may include issues related to

⁹ Since 2004 France is operating a reference pricing scheme for pharmaceuticals.

quality of care, safety and financial performance (i.e. use of public resources). A Ministry department has been created to recruit and train auditors for this purpose.

The strong role of the Ministry mirrors the role of the 'state' (i.e. the public authorities) in French public life and there is a longstanding expectation that the state provides for the wellbeing of its citizens. The control of the Ministry of Health over the health system is greater than in other countries in which public funding is organised through (non-state) social health insurance.

This role may be illustrated further by the Ministry's response to the 2003 heat wave crisis which was associated with approximately 15,000 deaths (of mainly older people). Hospitals were unable to cope with the massive influx of patients and many died due to inadequate treatment capacity. Others died in nursing homes or at home unable to access medical care in time. As August is the official holiday month in France, hospital staff as well as personnel working in public administration and the Ministry (including the Minister himself) were absent in large numbers. Health authorities at all levels failed to recognise the extent of the crisis until reports of overcrowded emergency departments and morgues became omnipresent (government officials were later criticised for initially classifying these deaths as 'natural').²³

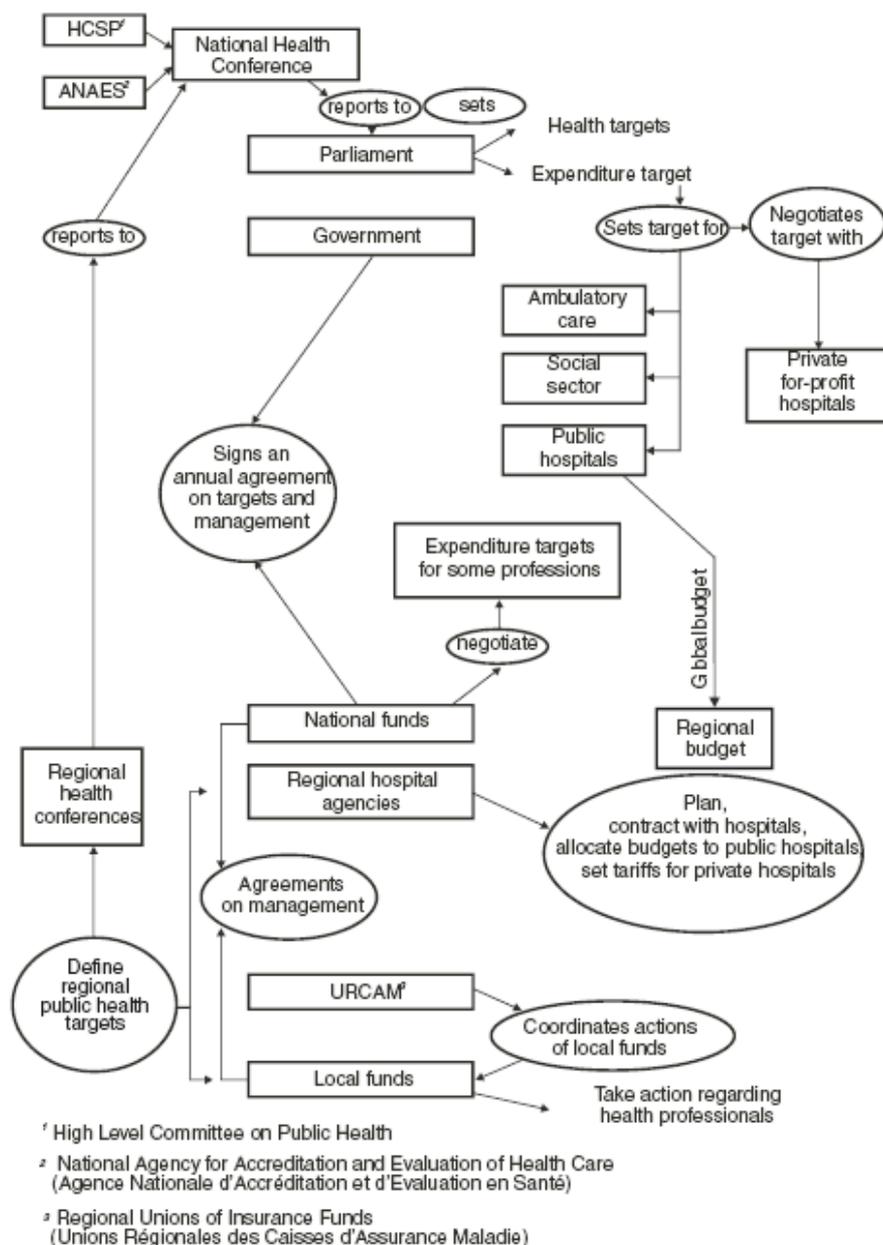
The failure of the system adequately to respond to the heat wave caused a political crisis. As an immediate consequence the director general for health who is formally responsible for the functioning of the health system had to resign.²⁴ Ministers were recalled from holidays and the Prime Minister announced an emergency plan ('Plan Blanc') normally reserved for disasters, epidemics and terrorist attacks. This plan involved recalling doctors from holidays, the recruitment of temporary staff and the organisation of additional emergency and mortuary capacity.²⁵

Long-term responses involved the development of preparedness plans at all levels (national, regional, local administration and within organisations), including new arrangements between hospitals and nursing homes and for older people living at home. Additional funds were made available to scale up organisational responses (e.g. for paying additional health staff) and to improve facilities for older people. Prior to the heat wave many retirement and nursing homes had not been equipped with airconditioning. Preparedness plans now also include extensive awareness campaigns involving the mass media in informing the public about preventive actions.

The government was strongly criticised for its slow response to the crisis. Several public inquiries, including one by a parliamentary commission (*la commission d'enquête sur les conséquences sanitaires et sociales de la canicule*) were launched to investigate why the system failed adequately to address the health effects of the heat wave. A government commission concluded that information about the scale of the problem did not reach the government as quickly as it should have done because of a fragmentation of responsibilities between the Ministry of Health, other government departments and front-line staff.²⁶

The heat wave was extensively covered by the media. However, an analysis of media content showed that most reports focused on the economic and ecological effects of the heat and, later on, with the government's slowness to respond to the crisis.²⁷ It was noted that the media missed the opportunity to raise awareness of the public health issues surrounding high temperatures. The failure adequately to respond to the crisis was also interpreted as an illustration of the "absence of a public health culture in France" (p.876).

Figure 2.2: Organisation of the French health system¹⁸



Source: various.

Note: The High Level Committee on Public Health (HCSP) has been replaced by the High Council of Public Health. ANAES has been integrated into the newly-established High Authority for Health (HAS).

3. Germany

3.1. Roles and responsibilities

Legislative framework

The roles and responsibilities of the key actors in the German health system are mainly defined through legislation, in line with the tradition of the *Rechtsstaat* ('rule of law state'). The Basic Law (*Grundgesetz*) provides the legal foundation for the general principles shaping responsibilities in the health system, including a commitment to federalism and to the welfare state (*Sozialstaat*).^h

Responsibility for health system governance is shared by federal, state (*Länder*) and local authorities. The regulation of hospitals, for example, falls under the remit of the *Länder*. At federal, regional or local level, many tasks have been delegated to corporatist actors. The regional physicians associations are, for example, responsible for overseeing ambulatory care.ⁱ

The social code determines the leeway policy-makers at federal, state or local level have to develop rules and regulations while delegating responsibility for interpreting aspects of the law to specific bodies (for example, the Federal Joint Committee specifies the 'appropriateness' of health services through defining the benefits package; see below). Federal legislation relating to social welfare, including health care, is set out in a series of social code books. Social Code Book V defines the roles and responsibilities of all health system actors as they relate to social (publicly financed) health insurance. The social code also defines the entitlements of patients and broadly sets out the principles for the provision, organisation and financing of publicly-financed health care. This includes a commitment to solidarity in financing and providing health services; efficiency of service provision and insurance administration; and stability of contribution rates to sickness funds.²⁸ Social code books are amended each time a new law is passed.

Parliament

The parliament (the Federal Assembly, *Bundestag*) sets out the legislative framework of the health system. Most laws associated with health care reforms have to be confirmed by the Federal Council (*Bundesrat*) which represents the 16 state governments. Technically, the Federal Council is not a second chamber of parliament but a separate legislative body.

The Federal Assembly does not determine the budget for publicly-financed health care as this is largely left to the associations of sickness funds. The process is overseen by the Ministry of Health. From January 2009, central government will set a uniform contribution rate for all sickness funds (see below). The Federal Assembly will have the opportunity to consider the contribution rate. The influence of parliament on the budget for publicly-financed health care might therefore rise in future.

^h The term *Sozialstaat* denotes the responsibility of the state (i.e. its representatives) to ensure social protection and social justice for all citizens.

ⁱ Ambulatory care is provided by general practitioners and office-based specialists. Hospitals are public, private for-profit and private not-for-profit organisations.

Ministry of Health

Structure

The federal Ministry of Health in its current form was created in 2005, following general elections. From 2002 to 2005 it was part of the Ministry of Health and Social Security, which became the Ministry of Labour and Social Affairs in 2005. The Ministry of Health's key responsibility is to maintain, secure and advance an effective publicly-financed health system, including long-term care insurance.²⁹ Its main function is to reform the health system so as to improve the quality of care, strengthen the role of patients, ensure an efficient health system and stabilise contribution rates to sickness funds. The Ministry of Health is responsible for overseeing and steering the development of the health system and for drafting legislation, usually in co-operation with other health system stakeholders.

The Ministry of Health is led by the Minister of Health, two Parliamentary State Secretaries (elected members of parliament, they represent the Minister in the political arena) and the Permanent State Secretary (a senior civil servant who assumes technical responsibility for the Ministry's various areas of competence).

The Ministry of Health comprises five departments which largely reflect the Ministry's key responsibilities (Figure 3.1):²⁹

- Management, communication and strategy;
- Administration, European and international affairs;
- Pharmaceuticals, medical devices and biotechnology;
- Health care, health insurance and long-term care insurance;
- Prevention, health protection, disease control and biomedicine.

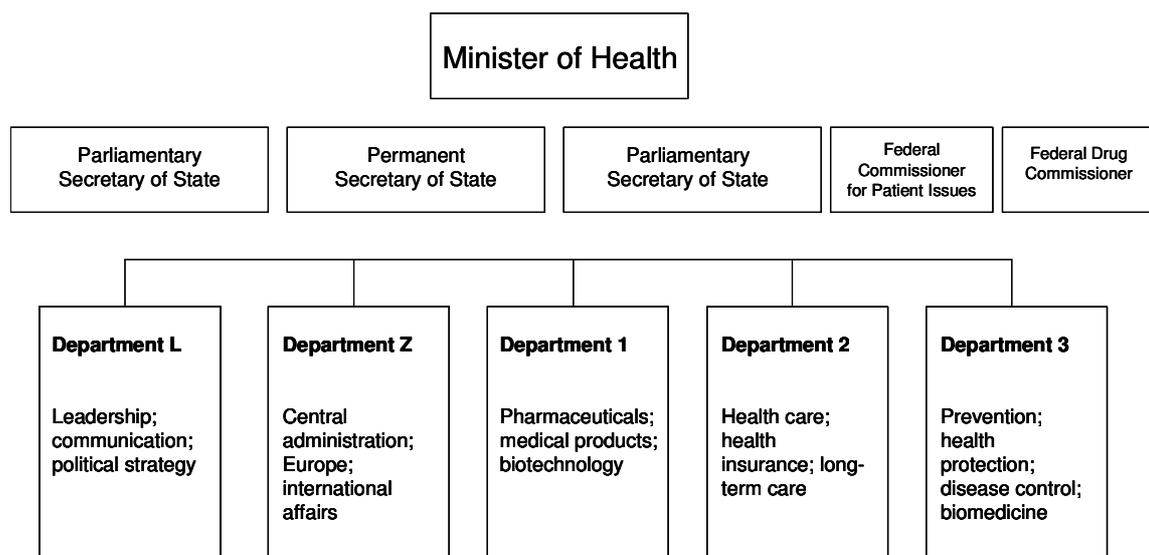


Figure 3.1 Organisational structure of the Ministry of Health

Two commissioners are linked to the Ministry of Health: the Federal Commissioner for Patient Issues and the Federal Drug Commissioner. The commissioners, both members of parliament appointed by the Federal Government on recommendation of the Minister of Health, are supported by separate administrative units. An Advisory Council on the Assessment of Developments in the Health Care System regularly reports to the Ministry of Health (see Box 3.1).³⁰

Key responsibilities

The federal Ministry of Health is not directly responsible for ensuring access to health care. This function has been delegated to the federal states (*Länder*) and corporatist actors. The Ministry is usually not represented in the decision-making bodies of the publicly-financed health system, the statutory long-term care insurance scheme or the statutory accident insurance scheme. However, the federal government has decision-making powers and financial duties in relation to statutory unemployment insurance. The Ministry's influence on health services is therefore indirect and its main responsibility is to secure and maintain the publicly-financed health system.

Key policy areas under the remit of the federal Ministry of Health include:

- prevention, disease control and biomedical regulation;
- supervision and licensing of pharmaceuticals, medical devices and biotechnology;
- health and health system monitoring;
- development of new models of health service provision;
- drug and addiction policies;
- licensing of health professionals and regulating standards for education and training;
- European and international health policy.

Accountability

The Minister of Health is accountable to the Chancellor (*Bundeskanzler*) and, as a member of the Cabinet, to the parliament.

Health strategy

The Ministry of Health does not directly develop a comprehensive health strategy, reflecting its limited role in health system governance.

In 2003 the Ministry commissioned a project with the aim of developing health strategies (so-called 'health goals') for a number of health areas. This project involves a multitude of health system stakeholders, including representatives of sickness funds, private health insurers, statutory and private long-term care insurers, the health professions, hospital associations, ambulatory care organisations and others. Until 2006, the project was funded by the Ministry; since then funding has been provided by a joint association of corporatist actors. Strategies have so far been developed for six areas: diabetes; breast cancer; depression; smoking cessation; child development; patient empowerment. Strategies for vaccination, chronic back

pain and cardiac infarction are in planning. Strategies are not binding, but it is hoped that involving a large number of stakeholders will promote their implementation.³¹

Human resources

The Ministry has about 600 staff. Two thirds are based in the former capital Bonn. The Minister, many senior executives and most core administrative units are based in Berlin.

Minister of Health, senior executives and advisors

Over the past 15 years, the post of the Minister of Health has become increasingly high-profile. Politically, the position is 'risky' given the high visibility of the Ministry in charge of a topic that receives substantial public attention on one hand and the limited control of the Ministry over the health system on the other. The 'success' of a health minister not only depends on his/her personality and authority and the political position of the government but also on the willingness of other health system stakeholders to co-operate and to support a government proposal. Thus, a health minister may be most 'successful' if s/he is a capable broker of stakeholder interests.

Parliamentary State Secretaries are by definition political posts and candidates are typically appointed following negotiations between the political parties which form the government.

The vast majority of staff at the Ministry are career civil servants; most of them are trained in law. The main exceptions are usually the head of the Minister's office, the personal assistant to the Minister and his/her media spokesperson who are typically directly appointed by the Minister. Some of the more 'exposed' senior positions, notably the post of the Permanent Secretary of State and the head of the Department of Health Care, Health Insurance and Long-Term Care Insurance, may be considered 'political' despite their formal status as civil servants. These positions are likely to be replaced with a new incoming government.

Agencies subordinate to the Ministry of Health

The *Federal Institute for Pharmaceuticals and Medical Devices (BfArM)* licenses pharmaceuticals and supervises the safety of pharmaceuticals and medical devices.³⁰

The *Federal Institute for Sera and Vaccines (Paul-Ehrlich-Institut)* is responsible for implementing the medicinal product legislation as it relates to licensing biomedical medicinal products, approving clinical trials of medicinal products for human use and processing applications for marketing authorisation.

The *Federal Centre for Health Education (BZgA)* is responsible for coordinating and strengthening health education, through developing and implementing principles, guidelines and strategies for health education, and for providing training and further education for those active in health education.³²

The *German Institute for Medical Documentation and Information (DIMDI)* provides information to the public and professionals in all fields of the life sciences, including health technology assessment reports.

Robert Koch Institut (RKI) is responsible for disease control and prevention. Its role was extended in 2001, adding tasks related to monitoring, co-ordinating

interventions, international co-operation, risk communication and microbiological and epidemiological research.³⁰

Other federal ministries and agencies

The *Federal Insurance Office* oversees the activities of sickness funds and other social health insurance organisations at federal level. It reports to the Ministry of Labour and Social Affairs. It administers the system of financial redistribution between sickness funds through a risk adjustment scheme, accredits disease management programmes and allocates maternal benefit payments.³³

Box 3.1 Advisory Council on the Assessment of Developments in the Health Care System

The Advisory Council on the Assessment of Developments in the Health Care System (*Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen*, previously *Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen*) was originally formed in 1985 to inform the so-called 'Concerted action' in the health system. Council members are appointed for a limited (though not specified) period by the federal Minister of Health. Members (currently seven) are experts in the field of health care based at academic or independent research institutes. They represent different disciplines such as economics, medicine, social science and health care management. The Council's functions are set out by law (Social Code Book V). Its main task is to assess developments in the health system with an emphasis on identifying priorities to reduce under- and over-supply of health services and providing recommendations to improve the health system. The Ministry of Health can define the topics the council focuses on and request special reports. The Council's main output consists of reports to the Ministry of Health, which the Ministry presents to the parliament. The Council's role is merely advisory; its recommendations are not binding. However, some of its recent reports have been influential and several of their recommendations have been implemented. The most recent report, published in July 2007, focuses on cooperation and responsibility. It identifies a general lack of targeted health care as one of the key shortcomings of the German health system.

State (*Länder*) Ministries of Health

The federal structure is mainly represented by the 16 state governments (*Länder*) which are responsible for maintaining hospital infrastructure and for public health services, with the latter subject to certain federal laws concerning diseases that threaten public safety. Responsibility for public health services is often devolved to local governments. *Länder* are also responsible for undergraduate medical, dental and pharmaceutical education, the supervision of the regional physicians' chamber(s), the regional physicians' association(s) and sickness funds that operate in one *Land* only (sickness funds operating in several *Länder* are overseen by the Federal Insurance Office).

In 2007 all but three *Länder* governments had a ministry with 'health' in its name. However, none is exclusively concerned with health. In most *Länder* the relevant ministry is combined with social affairs and/or, less commonly, labour and/or family. Some *Länder* ministries are also responsible for consumer protection, environment, youth, pensioners and/or legal affairs. For example, in Lower Saxony health falls

under the remit of the Ministry for Social Affairs, Women, Family and Health.³⁴ The health division is further subdivided into six units responsible for: public health services, infectious diseases, environmental health, civil protection; health promotion; pharmaceuticals, medical devices, biotechnology; occupational health, consumer protection, drug abuse; hospitals; supervision of health professionals; and psychiatric care. In Bavaria, responsibilities for health and health care are divided between two ministries, with the Ministry of Labour and Social Affairs, Family and Women responsible for hospital care and the Ministry for the Environment, Health and Consumer Protection for public health.

The *Länder* coordinate their (public) health activities through the annual Conference of Health Ministers (*Gesundheitsministerkonferenz; GMK*).³⁵ The Conference of Health Ministers addresses regional and federal health policy developments and is normally attended by the federal Minister of Health and a representative from the Federal Council (*Bundesrat*). Each Land takes it in turn to chair the Conference of Health Ministers every year. The Conference is informed by the Working Group of Senior Health Officials which brings together the heads of the health departments of all *Länder* ministries, along with representatives from the federal Ministry of Health. The Working Group also provides regular assessments of health policy and public health issues and European developments. Although the formal role of the Conference of Health Ministers is limited (its decisions are not binding), it does make an important contribution to the federal and *Länder* health policy agenda.

Corporatist actors

The *Joint Federal Committee (Gemeinsamer Bundesausschuss, G-BA)* is the highest decision-making body in the health system at federal level. The Joint Federal Committee brings together nine representatives from the federal associations of sickness funds, nine representatives from the federal associations of provider groups (publicly-financed physicians – 4; dentists – 1; and hospitals – 4), and three independent members who also hold the chair. Members are nominated by the relevant federal association, while independent members are nominated either by the provider or the payer side. Joint Federal Committee meetings are also attended by up to nine representatives from patient organisations but their role is advisory and they do not have a vote in the decision-making process.

The Joint Federal Committee was established in 2004 as a result of the merger of several sector-specific committees at the federal level. It is mandated to carry out a number of regulatory tasks which are defined in Social Code Book V (§ 91-94). These include defining the publicly-financed benefits package and setting quality standards for ambulatory, inpatient and inter-sectoral health care. Decisions by the Joint Federal Committee are majority decisions. At present, the Joint Federal Committee meets its tasks through six panels relating to the different health sectors, each with decision-making powers. Its members are non-salaried. From 2008 the panel structure is to be replaced by a central decision-making body within the Joint Federal Committee, with the (independent) chair as the only full-time member.

The Joint Federal Committee is an independent legal entity and is not subordinate to the Ministry of Health. However, it is accountable to the Ministry of Health and its decisions must be submitted to the Ministry of Health. The Ministry of Health has a period of two months to veto any Joint Federal Committee decision, after which decisions will become effective through publication in the Federal Gazette (*Bundesanzeiger*).

Sickness funds

Sickness funds are bodies regulated by public law. All funds have non-profit status and are based on the principle of self-governance. Each fund collects contributions from its members. At present each fund also sets its own contribution rate. From 2009 the federal Ministry of Health will impose a nationally uniform contribution rate. Decisions about the level of the contribution rate will be based on analyses by an expert panel to be established at the Federal Insurance Office. The decision will take direct effect and will not require approval by the Federal Council (*Bundesrat*), although the government is required to inform the parliament (SGB V, §241). The new health fund will pool all contributions (which will continue to be collected by individual sickness funds) and allocate to the sickness funds a uniform capitation fee per insured person, adjusted for age, sex and health risk.

Most sickness funds are managed by an executive board (two full-time professional managers) responsible for day-to-day business and an administrative board of delegates which decides on the sickness fund's by-laws and regulations, approves the budget, sets the contribution rate and elects the executive board.³⁰ The administrative board is usually composed of representatives from both insureds (employees) and employers who are elected for six years. However, administrative boards of 'substitute' funds do not have employer representation.

Sickness funds are represented at *Länder* and federal level through joint associations. Associations are currently formed for each type of sickness fund. Sickness fund associations are subject to public law. *Länder* associations of sickness funds form federal associations (again one for each type of fund); they represent the interests of sickness funds and their regional associations at federal level, support the development of the legislative framework, arbitrate conflicts between member associations and co-ordinate data collection and statistics. They can also contract with other health system stakeholders. The federal associations of sickness funds are overseen by the Ministry of Health, which has delegated this task to the Federal Insurance Office. The role and responsibilities of sickness fund associations are defined in the Social Code Book V (§§ 207-219).

From July 2008, the federal associations of sickness funds will be replaced by a single organisation (*Spitzenverband Bund der Krankenkassen*).³⁶ This new organisation will assume most of the legal responsibilities of the federal associations^j and will be charged with a number of additional tasks, such as the development of a regulatory framework for competition between sickness funds as a means to control the effect of competition on quality and efficiency.

Providers

Corporatist institutions on the provider side are responsible for securing provision of all personal acute health care services. The physicians' and dentists' associations have corporatist monopolies and the mission to secure ambulatory care. This means that hospitals, communities, sickness funds and others do not have the right to provide ambulatory medical care except for purposes mandated by legislation or through joint commissions of payers and providers. However, this is slowly changing in the light of recent health care reforms.

The *Federal Association of Social Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV)* represents, at federal level, the interests of physicians and

^j The existing associations of sickness funds may remain but will operate under private law.

psychotherapists providing services in the ambulatory and hospital sectors of the publicly-financed health system. The federal association brings together the regional associations in each of the 16 *Länder*. Only North Rhine-Westfalia, the most populated of the 16 *Länder*, is represented by two associations.³⁰ Membership of a regional association is mandatory for physicians and psychotherapists who wish to qualify for reimbursement through the publicly-financed health system. Associations keep a register of all practising members.³⁷ There are separate associations for dentists.

The Federal Association of SHI-Physicians and its regional member associations are non-governmental bodies under public law.³⁷ Regional associations of SHI physicians have been mandated with a number of tasks defined in Social Code Book V, including:

- representing SHI physicians' interests in legislative processes at regional and federal level;
- negotiating collective contracts with the association of sickness funds and other parties; contracts with sickness fund associations cover almost all services provided by SHI physicians with the exception of integrated care services, which are negotiated directly between sickness funds and individual providers;
- determining and reviewing, in co-operation with sickness funds associations, the fee schedule for office-based doctors (*einheitlicher Bewertungsmaßstab, EBM*);
- participation in decisions to determine the benefits package of health services as a member of the Federal Joint Committee (G-BA).³⁷

The KBV is governed by a board comprised of two directors (elected for a period of six years) and an assembly of delegates (60 representatives of regional associations). Their role is to decide on policies, guidelines and regulations applying to issues which fall under the remit of the KBV. The KBV is a statutory body and its activities and those of its regional members are overseen by the federal Ministry of Health and relevant *Länder* authorities respectively.

The *German Hospital Association (Deutsche Krankenhausgesellschaft, DKG)* represents the interests of all hospitals providing care under the publicly-financed health system, including public, private for-profit and private non-profit organisations. At present, the national association brings together 16 *Länder* hospital associations (*Landeskrankenhausgesellschaften*) and 12 national associations representing different hospital bodies (e.g. private for-profit or private not-for-profit hospitals) (*Spitzenverbände der Krankenhausträger*). Formally, the DKG does not have the status of a quasi-public corporation, unlike the *Federal Association of SHI Physicians*; it is governed under private law. However, it has increasingly been integrated into decision-making bodies of the publicly-financed health system, such as the Federal Joint Committee, and it has been equipped with a number of legal responsibilities.³⁰

The provision of hospital care is negotiated at the *Länder* level, with the relevant state hospital association and/or the national hospital association entering into contracts with sickness fund associations. These contracts regulate the general conditions of service provision in hospital. They also define criteria for hospital admission and discharge; the services eligible for SHI reimbursement and the level of

reimbursement; the appropriate length of inpatient stays; principles of efficiency and quality control; social assistance and counselling of inpatients; organisation of care pathways from hospital to long-term care; and eligibility for, type and scope of fertility treatment (SGB V, § 112). Contracts are binding for both sickness funds and hospitals, provided the services are delivered to SHI patients and are included in the hospital plan of a given *Land*.

Also at *Länder* level, hospital associations negotiate contracts with sickness fund associations and associations of SHI physicians. These contracts regulate co-operation between office-based physicians and hospitals.

Other key stakeholders

Professional chambers are responsible for overseeing secondary training, accreditation and continuous education and for setting professional, ethical and community relations standards.³⁰ They are not part of the SHI system and are therefore subject to private law. Their decisions are not binding and have the status of recommendations.

A large number of private and voluntary organisations and interests groups influence health policy through lobbying and/or through official consultation. Medical scientific and professional organisations cover the entire spectrum of medical specialities and health-related professionals, including nurses, pharmacists and psychotherapists. Welfare organisations play an important role as providers of hospital and nursing home care and organise most ambulance transports. They are represented at federal level through the Federal Alliance of Voluntary Welfare Organisations.

Private health insurance companies are represented by the Association of Private Health Insurers (*Verband der Privaten Krankenversicherungen*, PKV). Pharmaceutical companies have formed several influential organisations, including the Association of Research-based Pharmaceutical Companies, which is represented in stakeholder consultations on pharmaceutical pricing.

Patient organisations represent a wide spectrum of patient interests and have become increasingly involved in consultations. Since 2004, the four largest organisations have been consultative members of the Federal Joint Committee.

3.2 Key governance functions

Defining the benefits package

Within the publicly-financed health system, patient entitlements are broadly defined by the Social Code Book V; entitlements include preventive care, services associated with early diagnosis, treatment of disease, reproductive services (including contraception, sterilisation and abortion), occupational health and a small number of cash benefits, mainly for rehabilitation and social care.

Publicly-financed entitlements are further specified by the Joint Federal Committee as one of its regulatory tasks; these include all aspects of medical care, dental care, medical diagnostics, maternal care, new technologies, pharmaceuticals and medical devices, hospital care and home nursing, medical rehabilitation, fertility treatment, patient transport, palliative care and vaccination. The Joint Federal Committee has to consult the relevant provider associations before making a decision. The Ministry of

Health has the authority to veto decisions by the Joint Federal Committee. Decisions become effective through publication in the Federal Gazette.

Some pharmaceuticals for minor ailments are excluded from the benefits package, such as drugs for common colds that are sold over-the-counter.³⁰ These exclusions are defined in Social Code Book V.

Overall health care financing

(a) Collection of funds

Sickness funds play a significant role in the management of health care financing. Contributions paid by employers and employees are levied on earnings and are compulsory for employees earning less than a specified threshold (currently €42,750 per year)³⁰. Employees with earnings above the threshold and their dependants (about 26% of the population) can choose to be publicly or privately insured; most choose public insurance because it provides free cover for dependants.^{38,39} For certain groups of people, including students, pensioners and the unemployed, public agencies pay contributions to sickness funds.

At present, each sickness fund (currently around 250) sets its own contribution rate and collects the contributions. If expenditures exceed revenues in a given year, they are required, by law, to increase their contribution rate. Sickness funds may not incur deficits and do not normally receive tax subsidies; they are fully financial liable. Only if a fund runs into severe financial problems, threatening its sustainability, it is to be supported financially by its respective association.³⁰

In 2005 out of pocket payments and private health insurance accounted for 13.8% and 9.1% of total expenditure on health respectively.²² Decisions about the application and level of statutory user charges are made through the federal parliamentary process. Proposals for change developed by the Federal Ministry of Health are formally voted on in parliament and any change in legislation must be approved by the Federal Council (the parliamentary body representing the *Länder*). Some laws grant power to the Federal Minister of Health to extend the new legislation through decrees, which do not require renewed parliamentary approval. For example, the Health Care Reform Act of 1989 empowered the Federal Minister of Health to extend the negative list for pharmaceuticals by decree (§ 34 SGB V). Sickness funds have no power to set user charges (in contrast to private health insurers, who have considerable discretion in this area). Physicians are also prevented from applying user charges beyond those stipulated in law. Private health insurance plays a substitutive role and is heavily regulated.

(b) Allocation of funding and budget setting

Sickness funds are subject to a redistribution mechanism managed by the Federal Insurance Office, which effectively pools contributions and re-allocates them after adjusting for age, sex, disability pension status and (since 2002) participation in disease management programmes. The sickness funds set budgets for ambulatory and hospital care in co-operation with the Association of SHI Physicians (ambulatory care) and the German Hospital Association (hospital care). They distribute the budget for ambulatory care (i.e. services provided by office-based doctors) to the regional associations of SHI physicians, typically based on capitation fee per insured, which reimburse SHI physicians for each service delivered using a uniform-value scale (*Einheitlicher Bewertungsmaßstab*, EBM).³⁰ The EBM is nationally uniform

and is set Valuation Committee (*Bewertungsausschuss*) formed by the Federal Association of SHI Physicians and the federal associations of sickness funds.⁴⁰

Price setting

(a) Pharmaceuticals

Prices for pharmaceuticals are generally not fixed; however, a complex set of regulations applies along the market chain. These include, for example fixed mark-ups for wholesalers and pharmacies.²⁸ Also, reimbursement levels are defined for many drugs under SHI by the G-BA.³⁰ Regulation of pharmaceutical pricing are set out in Social Code Book V.

Different pricing mechanisms apply to pharmaceuticals used in hospitals (i.e. inpatient care) and in ambulatory care. Prices for hospital drugs are negotiated directly between hospitals and pharmaceutical manufacturers. In the ambulatory sector, most drugs are exclusively sold in pharmacies. Prices are generally set by the manufacturer both for patented and generic drugs. For generic drugs, levels for SHI reimbursement are set through reference pricing. The G-BA determines the groups of drugs to which reference pricing applies; the federal associations of sickness funds jointly set the reference price per group. Patented drugs are excluded from reference pricing if there is evidence for additional therapeutic benefit.³⁶

The Ministry of Health has occasionally been involved in pharmaceutical pricing, but it requires an explicit legal mandate to do so. This is set out in the Social Code Book.

(b) Health services in ambulatory and hospital care

Services provided by physicians in ambulatory care (general practitioners and specialists) are reimbursed on a fee-for-service basis. The levels of fees are determined through negotiation between the regional associations of sickness funds and the regional associations of SHI physicians (KV). Separate fee schedules apply for SHI and private health insurance.

Hospital services are reimbursed using Diagnosis-Related Groups (DRGs) and a number of specific grants to compensate for costs related to activities such as training and research. Prices per DRG are determined at regional level through negotiations between the regional associations of sickness funds, the regional associations of private health insurance funds and the regional hospital associations. Prices are set by developing a base rate (the average cost per case) per state, weighted per DRG.⁴¹ Specific grants are negotiated, partly, between regional sickness funds and individual hospitals or between the respective associations at regional or federal level.

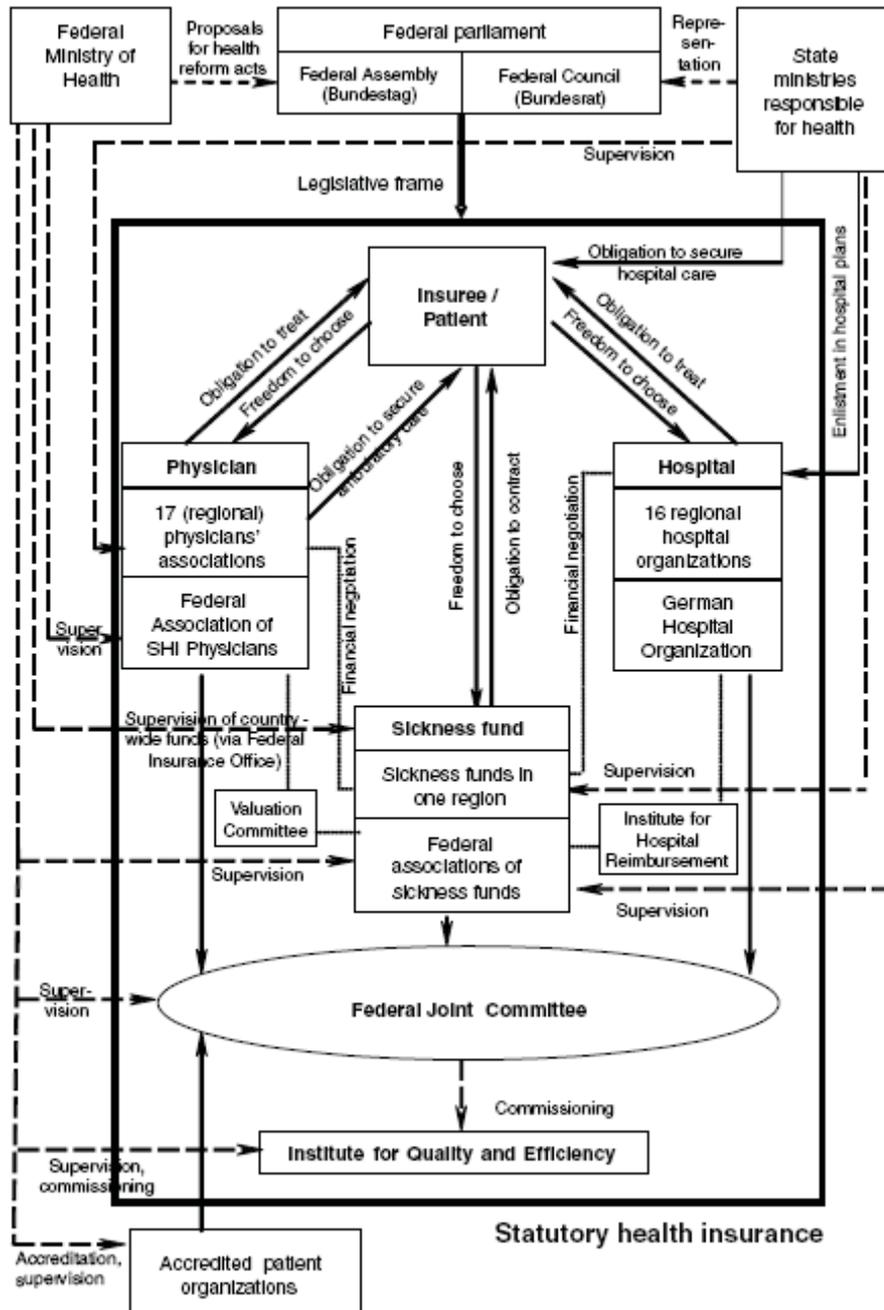
For services reimbursed under private health insurance fee levels are determined by the Federal Ministry of Health which is advised by the Federal Physicians' Chamber.³⁰ Fee levels include minimum and maximum charge rates.

(c) Salaries of nurses and doctors

Salaries for nurses and doctors employed in public or private not-for-profit hospitals are determined through negotiation between the associations of local and regional public employers (representing public hospitals owned by districts and regions) and unions.

Salaries in private for-profit hospitals are flexible and may be negotiated individually. Office-based doctors are paid on a fee-for-service basis (see above).

Figure 3.2: Key actors in the German health system



4. New Zealand

4.1 Roles and responsibilities

Legislative framework

Responsibilities in the public health system are defined through a number of laws, most recently through the 2000 New Zealand Public Health and Disability Act (NZPHDA).⁴² The NZPHDA established the current structure of the public health system by delegating the organisation of health services to 21 newly created District Health Boards (DHBs).

The NZPHDA places responsibility on the Minister of Health (supported and advised by the Ministry of Health) to determine the health and disability strategies and strategies for standards and quality assurance, to establish committees to support the implementation of the Act and to enter into Crown funding agreements with Crown entities (such as DHBs). The Act also defines the Minister's responsibility for organising consultations before introducing any strategy and for annually reporting on progress in implementing the Act.

The role of the Ministry towards other health system actors is further specified through an Operational Policy Framework, which sets out the accountability requirements of DHBs. For example, the Ministry approves District Strategic and District Annual Plans. The current framework came into effect in July 2003.

Parliament

The parliament provides legislation that defines the organisation and structure of the public health system.^k The parliament also approves the annual budget for publicly funded health care.

A Parliamentary Health Select Committee scrutinises the performance of the Ministry of Health and the health system and conducts detailed inquiries into contemporary health issues.

Ministry of Health

Structure

In July 2007 the Ministry of Health was reorganised to strengthen its leadership function following the recommendations of a 2006 capacity and capability review.⁴³ However, there has been no fundamental alteration of the scope of the Ministry's responsibilities. The intention was to organise the Ministry more explicitly around responsibilities for health system structure, policy design, accountability, performance support and regulation and to support the implementation of the government's key strategies and policies through DHBs.⁴⁴ The new structure comprises the following ten directorates (Figure 4.1).

^k The Parliament formally consists of the Queen and the New Zealand House of Representatives; a second chamber, the Legislative Council was abolished in 1951.

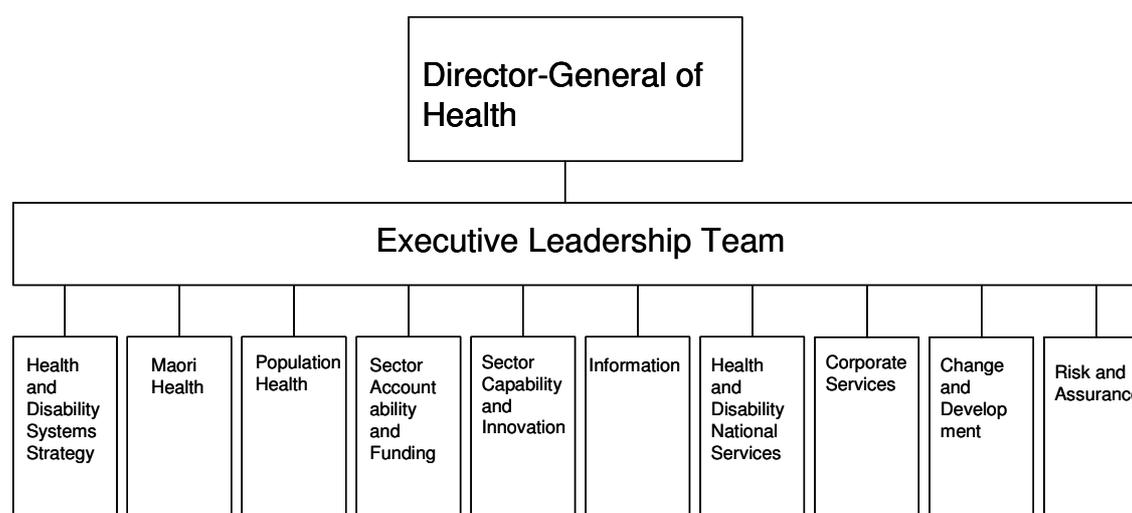


Figure 4.1 Structure of the Ministry of Health

- the *Health and Disability Systems Strategy Directorate* is responsible for providing strategic advice on health, public health and disability issues adapting a whole-system perspective;
- the *Maori Health Directorate* provides advice on Maori health;
- the *Population Health Directorate* is responsible for translating the strategic decisions of the Government into policy settings and operational frameworks;
- the *Sector Accountability and Funding Directorate* is responsible for funding, monitoring and ensuring that the publicly funded health sector is compliant with accountability expectations. It also oversees adherence to health regulation;
- the *Sector Capability and Innovation Directorate* supports the implementation, capacity building and exchange of innovations in the health system in view of strategic policy priorities;
- the *Information Directorate* aims to consolidate the capacity to manage information systems in the public health system and ensures access to key information databases held by the Ministry;
- the *Health and Disability National Services Directorate* is responsible for planning and funding services not currently funded through District Health Boards, including disability support services, public health services, specific personal health services and the national screening programme;
- the *Corporate Services Directorate* provides support to directorates to ensure that they operate effectively; functions include legal advice, communications and government relations;

- the *Change and Development Office* oversees and co-ordinates the implementation of the new structure of the Ministry;
- the *Risk and Assurance Group* provides independent advice to the Director-General (the permanent head of the Ministry) on strategic and operational risks in the Ministry.

The restructuring also involves changes in the leadership structures⁴⁵, now comprising:

- an *Executive Leadership Team (ELT)* as the key decision-making body of second tier managers responsible for all strategic decisions that have an impact across the Ministry and/or the health system;
- a *Leadership Forum*, which meets periodically to discuss the Ministry's performance and progress;
- a *Professional Advisory Group*, which advises the Director-General of Health and the Executive Leadership Team on key issues affecting the Ministry and the health system.

The precise functions and composition of new leadership structures is as yet to be defined, with the exception of the Executive Leadership Team, whose role is further defined as:⁴⁵

- to determine the Ministry's strategic direction and priorities;
- to lead strategies to achieve the Ministry's strategic goals;
- to evaluate progress towards these goals;
- to lead positive change within the Ministry;
- to lead the development of Ministry culture;
- to manage key relationships.

The ELT is to be formed by the Deputy General Director plus the Principal Medical Advisor and the chair of the Professional Advisory Group. The present (interim) ELT comprises the Director General of Health and the (Deputy) Director Generals of nine directorates (excluding the Risk and Assurance Group).

The Ministry of Health has five regional offices in Auckland, Hamilton, Wellington, Christchurch and Dunedin.

Key responsibilities

The Ministry of Health is responsible for overseeing the health system and for advising the Minister of Health on the relevant policy frameworks.

Key responsibilities are:

- to provide policy advice to the Minister on improving population health (including policies aimed at overcoming health inequalities for ethnic minority groups);

- to act as the Minister's agent;
- to monitor the performance of District Health Boards and health sector Crown entities against objectives agreed with the government;
- to implement, administer and enforce legislation and regulation;
- to plan and fund publicly-funded health services, disability support services and other service areas for which responsibility is centrally retained;
- to facilitate co-operation and co-ordination within and across sectors relevant to population health (e.g. education);
- to provide politically neutral advice to ministers about health sector performance;
- to provide advice on health-related biosecurity issues.^{44,46}

Human resources

The number of personnel working at the Ministry of Health has been estimated at 900. This includes staff working for the Ministry's external offices and business units but excludes Crown entities.

Accountability

The Minister of Health is directly accountable to the Prime Minister and the parliament. On behalf of the Minister, the Ministry of Health publishes an annual health report documenting the Ministry's financial and non-financial performance. The report on non-financial performance, the 'Statement of Objectives and Service Performance', details sector progress towards the objectives set out in the health strategy (see below) and the Minister's statement of intent. In 2004/5, the annual reports for the health sector and the disability sector were merged.⁴⁷

Health strategy

In 2000, the Ministry of Health developed a comprehensive New Zealand Health Strategy, mapping out the vision for the entire health system for the next decade.⁴⁸ The national health strategy sets out the principles, goals and objectives for the health system and creates a policy framework within which DHBs and other organisations across the health sector operate. It also highlights selected priority areas, such as cancer, diabetes, obesity, smoking and Maori health. The strategy does not detail how specific objectives have to be met or how services should be provided. For some areas the Ministry has developed additional strategies ("toolkits") and, in some cases, specific action plans (e.g. for cancer care). However, toolkits provide policy guidance rather than binding rules and targets are typically not quantified. The Ministry reports annually on progress in implementing the strategy, mainly by documenting the activities undertaken by DHBs, Primary Health Organisations and other organisations at national and local level.⁴⁹

Minister of Health, senior executives and advisors

The post of the Minister of Health ranks among the most senior appointments and has lately been taken by experienced and trusted colleagues of the Prime Minister

from the majority Labour party. The position is considered 'prestigious', although it is not on a par with ministers of finance or social development.

The Ministry's chief executive is appointed by the State Services Commission based on his/her merit. The Commission is led by the State Services Commissioner who is responsible to the Minister of State Services; its role is to ensure that the permanent public service is politically neutral. Thus, the governing political parties are not involved in the selection process. Other senior management positions are appointed by the Minister. Interview panels normally include senior staff from other ministries such as the Treasury or the Department of the Prime Minister and Cabinet.

Since creating the first Chief Advisor position in 1993, the number of advisor positions has increased and now covers 12 broad areas as detailed below. The Ministry's chief advisors are expected to be leaders in their fields and to act as representatives of the Ministry in the health and disability sector. Their role also involves representing the views of health professionals and other health system stakeholders.⁴⁴

There are currently 13 chief advisors covering: clinical services; nursing; disability support services; media; Maori health; child and youth health; mental health; oral health; general practice; pacific health; health information strategy and policy; and public health (two positions, also including the Director of Public Health at the Ministry). This group will also act as the recently established Professional Advisory Group, at least in the first instance, with the chair of the group to attend ELT meetings.

Subordinate agencies

External offices and business units

The Ministry of Health is supported by eight external offices and business units. Business units operate separately from Ministry, providing specialist functions but not policy advice:

- the *Clinical Training Agency*: provides funding for Post Entry Clinical Training programmes (i.e. for continuous professional training);
- *HealthCER*: responsible for certification of hospital care services and residential care home services;
- *HealthPAC* (Health Payments, Agreements and Compliance): provides services to health funders;
- *Medsafe* (New Zealand Medicines and Medical Devices Safety Authority): responsible for the regulation of therapeutic products;
- the *National Radiation Laboratory*: provides services and advice on matters concerning exposure to radiation;
- the *National Screening Unit*: administers New Zealand's health screening programmes (e.g. national breast screening programme), responsible for the safety, effectiveness and quality of health and disability screening programmes;

- *New Zealand Health Information Service*: responsible for the collection and dissemination of health-related data;
- *Public Health Intelligence*: statutory responsibility for monitoring the health of the New Zealand population.

Crown Entities¹ in the field of health

The *Accident Compensation Corporation (ACC)* provides work-related injury cover for all New Zealand citizens, residents and temporary visitors to New Zealand through a system of social insurance accounting for around 10% of total health spending. Unlike other crown entities the ACC is led by a Minister who is accountable to the Prime Minister and parliament, but not to the Minister of Health.

The *Pharmaceutical Management Agency (PHARMAC)* is funded by the Ministry of health and manages the pharmaceutical schedule on its behalf, including negotiating prices and purchasing subsidised drugs. It promotes the responsible use of pharmaceuticals and determines the level of public subsidy for eligible patients who have been prescribed pharmaceuticals by their general practitioner.

The *Health and Disability Commissioner* promotes the rights and responsibilities of consumers and providers, resolves complaints and investigates violations of the Code of Patients' Rights.⁴⁴ The Commissioner is independent from the Ministry and responsible to the Minister of Health only.⁴⁶

The *Crown Health Financing Agency (CHFA)* assists District Health Boards in maintaining financial sustainability through a range of financial services and advice. Services include public-sector loans, advice on the disposal or acquisition of property and a range of residual functions on behalf of the government.⁵⁰

The *Health Research Council of New Zealand (HRC)* manages the Government's investment in health research. The HRC falls under the remit of the Minister of Health and is independent of the Ministry of Health. Its budget is primarily controlled by the Ministry of Research, Science and Technology (MORST).

Other Crown entities include: the *Health Sponsorship Council (HSC)*, the *Institute of Environmental Science and Research (ESR)*; the *Mental Health Commission*; and the *New Zealand Blood Service (NZBS)*.

Ministerial Health Advisory Committees

The New Zealand Minister of Health is further informed by a number of expert advisory committees, currently totalling ten. Advisory committees bring together health professionals, lay representatives and academics who contribute on an honorary basis.

The *National Health Committee* incorporates the Public Health Advisory Committee and advises the Minister of Health on health services, personal health services and disability services that should be funded and/or subsidised under the public system. It also advises on regulatory matters relating to public health.⁴⁴

¹ A Crown entity is a type of organisation that forms part of New Zealand's state sector. Crown entities in the field of health are not part of the Ministry of Health.

The *Health Information Strategy Action Committee (HISAC)* is a ministerial advisory committee that provides governance and leadership for the implementation of the Health Information Strategy for New Zealand.

The *Pharmacology and Therapeutics Advisory Committee (PTAC)* evaluates the clinical evidence on the effectiveness of treatments to inform decisions of PHARMAC on changes to the pharmaceutical schedule.

The *Quality Improvement Committee (QIC)* advises the Ministry on matters related to epidemiology and quality standards. The Committee combines the functions of the (previous) National Health Epidemiology and the Quality Assurance Advisory Committees.

Others are: the *Advisory Committee on Assisted Reproductive Technology (ACART)*; the *Ethics Committee on Assisted Reproductive Technology (ECART)*; the *National Ethics Advisory Committee*; the *Perinatal and Maternal Mortality Review Committee (PMMRC)*; the *Child and Youth Mortality Review Committee*; and the *Cancer Control Council*.⁵¹

Other ministries

The *Treasury* has a fairly influential role in the New Zealand health system by controlling public health expenditure through the annual Budget process and ensuring value-for-money in the publicly funded health system. This is done through assessing budget applications from the Ministry of Health and providing second opinion policy advice to the Minister of Finance on policy proposals influencing resource use in the health sector. The Treasury also advises the Minister of Finance on capital investments to publicly owned providers.

The *Department of Labour, Health and Safety Section* provides guidelines to business on occupational health and safety, inspects workplaces, investigates accidents at work and ensures that employers and employees adhere to health and safety regulation.

The *Ministry of Social Development* provides social policy advice and services and is responsible for administering sickness benefits and the funding of medical care for war veterans.⁴⁶

The *Ministry of Maori Development* is concerned with improving the welfare, including health, of the Maori population. It also monitors the responsiveness of the Ministry of Health to Maori related matters.

Other ministries involved in specific aspects of the health system are: the *Ministry of Education*, the *Department of Corrections*, the *Department for Internal Affairs*, the *Ministry of Research, Science and Technology*, the *Ministry of Defence*, the *Ministry of Agriculture and Forestry*, the *Ministry of Fisheries*, the *Department of Conservation*, the *Ministry of Women's Affairs*, the *Ministry of Youth Affairs* and the *Ministry of Pacific Island Affairs*.

District Health Boards

The 21 *District Health Boards (DHBs)* are responsible for planning, organising and delivering publicly-funded health and disability services to the population of a specific geographical area and for purchasing services on its behalf.⁴⁴

DHBs operate within the regulatory framework set by the Minister of Health and implement national health policies and strategies, for example, the New Zealand Health Strategy 2000, the 2001 Primary Health Care Strategy and the 2002 Maori Health Strategy. DHBs are statutory corporations owned by the Crown and accountable to the Minister of Health. Accountability requirements are specified through a national operational policy framework and involve strategic five-year health plans, annual statements of intent, annual operational plans and regular monthly and quarterly reports.

DHBs are governed by a board. These comprise up to eleven board members of which seven are elected. Up to four members can be appointed by the Minister of Health. Elected members serve for three years and can be re-elected. Appointed members can serve a maximum of three consecutive terms.

The Minister of Health has the authority to directly intervene if s/he considers a DHB or individual members of a DHB to be underperforming. Interventions may involve the appointment of a Crown Monitor to report to the minister on the performance of the board, the replacement of the board with a commissioner, the dismissal of board members and the replacement of the chair or deputy chair of the board.^{46,52}

4.2 Key governance functions

Defining the benefits package

The definition of benefits to be reimbursed under the public system emerges in a complex way from the framework set by the Ministry of Health through national strategies, the Operational Policy Framework and policies aimed at specific services or patient groups. The Ministry also maintains so-called 'toolkits' that set out the features of a 'good' service in major services areas (for example, diabetes, coronary heart disease, similar to National Service Frameworks in England).

DHBs also influence the availability of services through their purchasing decisions. The New Zealand Guidelines Group (NZGG)^m produces guidelines for the use of DHBs as purchasers and of clinicians. These guidelines are not binding, however. Thus, with the exception of pharmaceuticals (see below) there is no explicit definition of a benefits a package.

The National Health Committee advises the Minister of Health on health priorities and on new and emerging technologies. The Committee's advisory role grew out of an unsuccessful attempt to define 'core services' (a minimum benefits package) through the then Core Services Committee in the early 1990s.

Pharmac has been mandated by the Ministry of Health to determine the eligibility of pharmaceuticals for public subsidy. Since 2000, Pharmac has been a stand-alone agency directly accountable to the Ministry. It has substantial independence in determining the most cost-effective range of drugs available in the public sector. Unlike the National Institute for Health and Clinical Excellence (NICE) in England, Pharmac negotiates prices and purchases pharmaceuticals on behalf of the government. Although there have been occasions when ministers have intervened in

^m The NZGG is an autonomous non-profit organisation set up to promote independent expert advice on clinical guidelines. The NZGG was established in 1996 by the National Health Committee but became independent in 1999.

Pharmac decisions (e.g. in order to fast-track drug approvals), political interventions are relatively rare.

Overall health care financing

The commitment to fund the public health system through taxation is based on national legislation set out in the NZ Public Health and Disability Act, 2000. The central government determines the annual budget for publicly-financed health care in the same way as other public services through a process of negotiation involving the Ministry of Health and the Treasury, and their respective Ministers ('Vote Health'). The level of funding for health is based on a 'sustainable funding path' formula, which takes into account a range of potential pressures on health expenditure (projected changes in population size and age structure, predicted price increases and the net effect of technological changes and efficiency gains). The annual budget is approved by parliament. The central government also sets the employer and employee levies that determine the budget of the Accident Compensation Corporation (ACC).

The Ministry of Health allocates the government health budget to 21 District health Boards (DHBs) using a risk-adjusted capitation formula based on population size, ethnicity, age structure and other population characteristics. Within their allocated budget, DHBs fund specific services for their populations, except for services that are purchased by the Ministry of Health (for example, highly specialised services). DHBs produce annual operational and strategic five-year plans that set out their priorities and specify how they intend to use the allocated resources. They have limited discretion in allocating resources as most of their funds are committed in advance to implementing national strategies, Ministerial priorities and requirements set out in the Operational Policy Framework.

Price setting

(a) Pharmaceuticals

Pharmac sets prices for most pharmaceuticals in the public sector; it determines the level of subsidy per item and negotiates prices to be paid to supplying pharmaceutical companies. Pharmac negotiates prices for all subsidised pharmaceuticals prescribed by a general practitioner and an increasing number of pharmaceuticals used in public hospitals.

(b) Services in ambulatory and hospital care

Prices for hospital services are locally determined through service agreements between DHBs and public hospitals. However, hospital budgets often take national benchmarking prices, set by the Ministry of Health, into account. These prices are also used to reimburse services between DHBs.

Fees for general practitioner services are negotiated between DHBs and their local primary health organisations (PHOs) for defined periods of time. The Minister proposes maximum fees; these are not binding. Local fee review committees review fee levels of individual practices that appear to be charging excessive fees. Practices can be exempt from public funding if they are found to be continuously overcharging. Thus fees for general practitioner services vary across the country depending on market circumstances and the effectiveness of local fee negotiation and oversight.

(c) Salaries for nurses and doctors

Salaries for nurses and doctors are largely determined through negotiations between professional associations/trade unions and employer organisations, so-called multi-employer collective agreements (MECAs). Since 2001, collective negotiations have gradually replaced the previous system of locally/individually negotiated salaries for health professionals employed in the public sector, indicating a shift from quasi-market to more collective approaches.

The Ministry of Health does not participate in these negotiations. There have been pressures (e.g. from unions or opposition parties) for the Ministry to become directly involved, for example following recent threats of industrial action by specialists arising from disagreements over pay. So far, the Ministry has resisted these pressures.

4.3 Government scope of action

In recent years, the government has attempted to strike a balance between central stewardship of the public health system and local responsibility and decision making. The government has a strong and continuous involvement in most aspects of the publicly financed health system. Following the 2000 Act, which abolished the internal market, central control has intensified in some areas while other governance functions have become more strongly decentralised. Examples for the former include a stronger involvement of government in aspects of capital investment, whereas the delegation of purchasing to DHBs signifies a move towards decentralisation.

At present, the government is trying to avoid intervening in areas that fall within the remit of DHBs or for which decisions are taken by a Crown entity. These include wage disputes, decisions to subsidise particular drugs and quality and safety issues arising from the treatment of individual patients. Although the Ministry of Health has retained the authority to intervene directly in many of these areas (for example by directing Pharmac to approve a drug and by replacing a DHB board), it tends to take a restrained approach to using this power. Much depends on the political position of the Government and the personality and authority of the Minister.

Instead, the Ministry of Health has tended to support DHBs to put in place effective processes and to strengthen their management capacity. The Ministry may also decide to intensify the monitoring of the performance of a DHB, which usually involves a scaling-up of the board's accountability and reporting duties towards the Ministry (the Ministry has a sliding scale of monitoring depending on the performance of DHBs). The Ministry also has the authority to replace individual board members or the entire board and to put a Crown monitor in charge of managing local operation. This may also apply to cases in which a DHB consistently fails to stay within budget.

The role of the Ministry may be illustrated by its responses to the following cases:

Failure of individual providers: Over the past months/years several incidents of poor clinical quality were reported to have occurred in the hospital at Wanganui, a small provincial hospital in the North of New Zealand. A patient died in 2004 after being discharged from the emergency department three times because of miscommunication between the referring general practitioner and (inexperienced) hospital staff.⁵³ In November 2006, it became known that more than 600 patients at the same hospital had missed out on specialist treatment because referral letters

were lost.⁵⁴ Another case involved a gynaecologist who had performed several failed sterilisation operations.⁵⁵

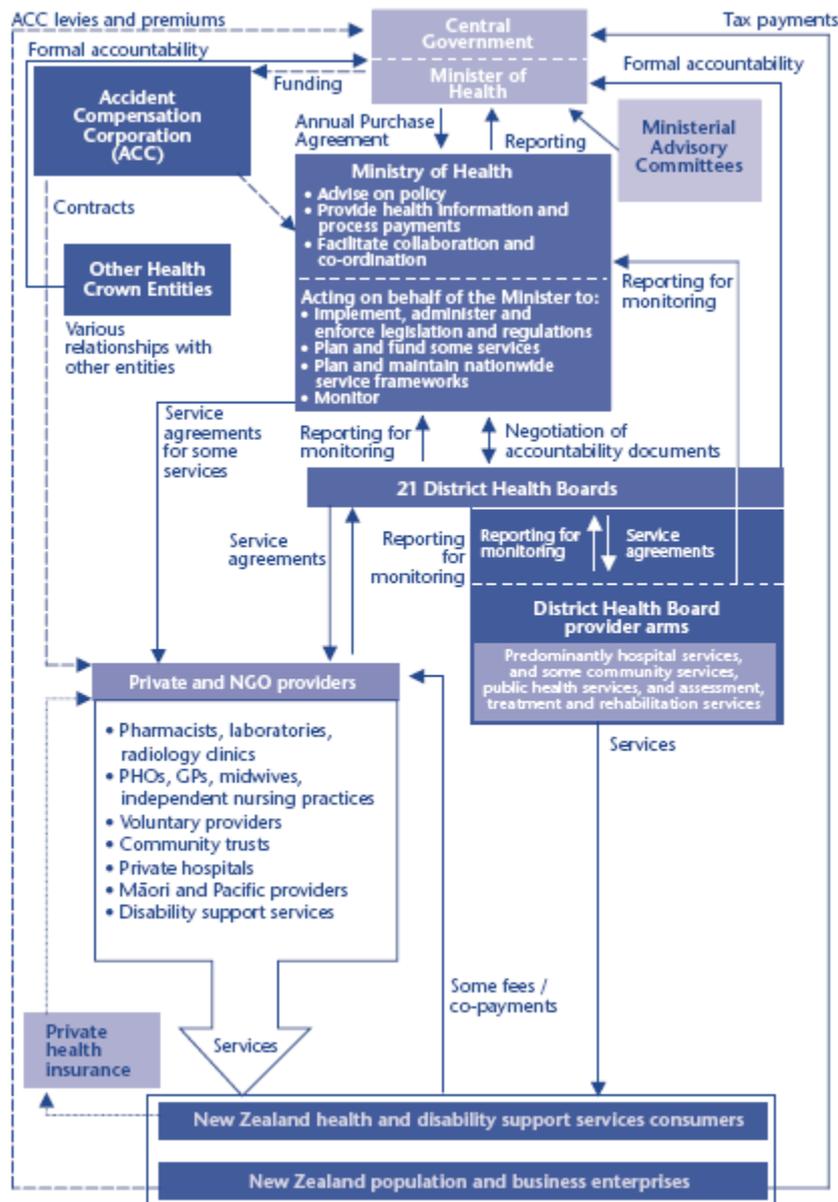
Following this sequence of failures the Minister of Health was pressurised by the opposition National Party to replace some members of the Wanganui DHB.⁵⁶ In response, the government launched several investigations into the performance of the hospital management and the DHB. The Ministry also placed the DHB on an intensive monitoring regime and appointed a senior advisor to assist the board in making the necessary changes.⁵⁶ The Health and Disability Commissioner, who can be called upon under the Code of Health and Disability Services Consumer Rights' (1996), has initiated an inquiry into the conduct of the gynaecologist.

A recently published external review of clinical quality in Wanganui hospital and an associated joint review of Wanganui District Health Board commissioned by Wanganui DHB and the Ministry of Health, concluded that clinical practice at the hospital was safe and quality systems in place were comparable to other hospitals in New Zealand.⁵⁷ However, the reviews were strongly criticised by several commentators, including the Royal Australian & New Zealand College of Obstetrics and Gynaecology, for being superficial and not going far enough.⁵⁸ The findings of the review by the Health and Disability Commissioner have not yet been released.

Closure of hospital departments: In the case of Kaitaia hospital, a 28-bed hospital in a rural community in Northland, the Ministry was asked to resolve a dispute between the DHB, the local community and the hospital staff following the DHB's decision to suspend all caesarean sections and after hours surgery because of specialist staff shortage.^{59,60} The Ministry required the DHB to ensure that local communities and staff were adequately consulted and commissioned a review of the safety and quality implications of the decision the DHB had taken. This case in part reflected a wider problem with recruiting and retaining specialist staff in small rural hospitals.

Failure of a DHB to secure services: The Ministry intervened in a recent dispute over a diagnostic contract between two private firms after it became apparent that a DHB had not adequately addressed a conflict of interest on the part of one of its board members.^{56,61} The DHB had to retender while the serving provider remained contracted in the interim.

Figure 4.2: Structure of the health system of New Zealand⁴⁴



5. Spain

5.1 Roles and responsibilities

Legislative framework

All residents in Spain have a constitutional entitlement to health care. The 1978 Spanish Constitution established the quasi-federalist structure of Spain giving substantial political autonomy to 17 regions (*autonomous communities*). However, the degree of decision-making power differs between regions, characterising the political system as one of 'asymmetric federalism'.⁶²

Health care in Spain is financed mainly through national taxation as established by the 1986 General Health Care Act (*Ley General de Sanidad*).⁶³ The Act also defines the principles of the Spanish National Health Service (NHS):

- access to health care for all residents free at the point of use;
- solidarity of public financing, mainly through general taxation;
- integration of diverse health service networks within the NHS (including public and some private providers);
- devolution of responsibilities to regions and, within regions, organisation of health services through health areas and basic health zones;
- an emphasis on primary care, integrating activities related to health promotion, prevention and rehabilitation at local level.⁶⁴

The 2001 Act on the Financing System of the Autonomous Communities devolved further powers by redefining the system of fiscal transfers from the centre to the regions. It has also provided all regions with the autonomy to organise regional health systems, including the ten smaller regions where health services had previously been managed centrally by INSALUD (*Instituto Nacional de la Salud*). INSALUD was abolished.

In 2002 parliament passed the Cohesion and Quality of the NHS Act (*Ley Cohesion y Calidad del Sistema Nacional de Salud*) as a means of addressing persisting regional health inequalities. The Act requires regions to enhance the co-ordination of regional health systems at federal level and has strengthened the role of the Interregional Council of the NHS (*Consejo Interterritorial del Sistema Nacional de Salud*, CISNS) (see below).⁶⁴

Parliament

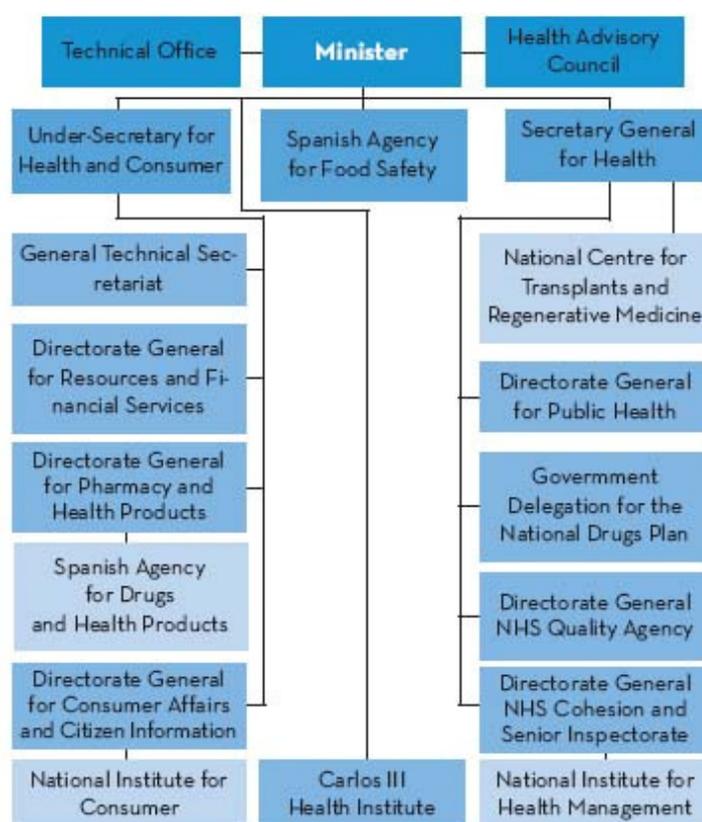
The national parliament (*Cortes Generales*) consists of two chambers, the Congress of Deputies, elected by proportional vote, and the Senate, whose members are partly elected by popular vote and partly appointed by the regions. The parliament develops and approves national legislation. This includes the Annual General Budget, which specifies the annual allocation to the regions of taxes levied at national level. The transfer of taxes is in the form of global budgets; allocations are not earmarked.

Ministry of Health

Structure

The Ministry of Health and Consumer Affairs has joint responsibility for overseeing health and consumer policies. The Ministry comprises six directorates, the Spanish Agency for Food Safety and the Carlos III Health Institute and the Government Delegation for the National Drug Plan, overseen by an Under-Secretary for Health and Consumer and a Secretary General for Health who are subordinate to the Minister of Health; the Carlos III Health Institute reports directly to the Minister. The Minister of Health is supported by the Health Advisory Council and a Technical Office. The Spanish Ministry of Health does not have a management board or specific committees mandated with issues that cut across the formal departmental structure (see Figure 5.1 for details).

Figure 5.1 Structure of the national Ministry of Health⁶⁵



Key responsibilities

The Ministry of Health is responsible for ensuring access to health services for all residents and for setting the overall policy framework under which regional health systems operate.⁶⁴ As noted earlier, responsibility for health care organisation has largely been devolved to the regions. However, the Ministry of Health has retained some key functions, including:

- responsibility for basic health legislation and for ensuring the co-ordination of regional health systems;

- overseeing the financing of regional health systems and advising on the regulation of the financial aspects of health care;
- defining the core benefits package of NHS services which all regions have to provide;
- pharmaceutical policy and pricing;
- overseeing training and promoting research;
- international health policies and health issues related to foreigners;
- general legislation regarding consumer protection.

Additional responsibilities are shared with other ministries. The *Ministry of Labour and Social Affairs* and the Ministry of Health jointly coordinate activities bridging health and social services. The *Ministry of Education* and the Ministry of Health share responsibility for the regulation of postgraduate training of medical professionals.

Accountability

The Minister of Health is accountable to the Prime Minister and parliament. There is no formal system for monitoring the performance of the Ministry of Health. The Ministry of Health is required to produce an annual activity report that contains some information on performance. However, this report does not assess performance systematically.

Following the 2002 Cohesion and Quality Act, the Ministry of Health began developing the 2006 Quality Plan for the NHS which introduced performance indicators. These indicators primarily measure population health and the performance of the health system in general. Notably, reports envisaged in the Quality Plan do not assign responsibilities in cases where regional health systems are found to be underperforming. Additional health system indicators have been agreed between the regions in the context of reporting requirements to the European Commission; thus the selection of key indicators reflects those used by, for example, EUROSTAT and other international organisations.⁶⁶

A National Health System Observatory based at the Agency for the Quality of the NHS (*Agencia de calidad del sistema nacional de salud*) reviews health system developments in collaboration with regional agencies. It produces annual reports on specific health policy topics. For example, the first report, published in 2003, provided an overview of the health system; the 2004 report focused on decentralisation and the 2005 report reviewed strategies for quality improvement across Europe. The Observatory does not act as an auditor, only as a monitor.

Health strategy

As responsibility for health system governance is largely devolved to the regions, the Ministry of Health's scope for influencing regional health systems is limited. However, attempts have recently been made to strengthen central functions. This involves a stronger role for the Ministry of Health in co-ordinating health policies and standard setting, for example through the 2002 Cohesion and Quality Act and the subsequent 2006 Quality Plan for the NHS. The 2006 Plan defined six strategic areas and twelve priorities for which policies will be designed and/or co-ordinated centrally (Table 5.1). A national plan on health and the environment is currently in preparation. However,

the role of the Ministry is mainly to propose standards to the regions and to influence regional standard setting through negotiations.

Table 5.1 Strategic areas and priorities for central policy

Strategic Area	Priority
1. Health promotion and prevention	<ul style="list-style-type: none"> ▪ Health protection ▪ Health and lifestyles
2. Equity	<ul style="list-style-type: none"> ▪ Promotion of health policies based on best practices ▪ Analysis of existing health policies and developing of proposals to reduce health inequalities (which have to include a gender perspective)
3. Human resources	<ul style="list-style-type: none"> ▪ Ensuring that the supply of human resources meets the demand for health services
4. Clinical excellence	<ul style="list-style-type: none"> ▪ Assessment of clinical technologies and protocols for clinical and managerial decision-making ▪ Licensing and auditing of health premises and services ▪ Improving patient safety on NHS premises ▪ Improving care for patient with specific conditions ▪ Improving clinical practice
5. Information and communication technologies	<ul style="list-style-type: none"> ▪ Internet-based information services
6. Transparency	<ul style="list-style-type: none"> ▪ Designing a reliable, timely and accessible NHS information system

Human resources

The number of Ministry of Health personnel has been estimated to be approximately 1,100. This excludes staff working in regional offices and Ministry of Health-affiliated agencies.

Minister of Health, senior executives and political advisors

The position of the Minister of Health does not rank high in the hierarchy of government ministries and the post has a reputation for not attracting political 'heavyweights'.

Senior civil servants / executives are usually appointed by the Minister of Health. Many of these appointments are 'political' (e.g. as a reward for loyalty during elections) and the body of non-partisan civil servants is comparatively small. Thus political appointments are not confined to the higher echelons of the public service.

Political advisors typically have one of the following two functions. They provide expertise directly to the ministerial cabinet through the Health Advisory Board (*Consejo Asesor de Sanidad*) or participate in 'ad-hoc' advisory committees to the Minister. These committees usually provide expertise on specific policy topics. Examples include stem cell research, therapeutic use of growth hormones, living will / advance directives. Advisors are normally appointed by the Minister. They may be civil servants from the local, regional or national public administration who are

seconded for a certain period or they may be external experts on a temporary contract. Members of expert committees normally qualify through their expertise and reputation. The majority of political advisors have no decision-making power. Advisors with civil servant status may, however, be equipped with additional executive authority.

Subordinate national agencies

The *Institute of Health Carlos III* is responsible for promoting and co-ordinating bio-medical research; training of personnel in public health and health services management; provision of public health services; health information; health technology assessment; scientific and technical accreditation; and technical advisory functions.⁶⁴ The Institute performs these roles through three subordinate agencies (the Agency for Assessment of Health Technologies,ⁿ the National School of Public Health and the Health Research Fund) and a set of National Centres which cover a series of research and service areas (epidemiology; clinical research and preventive medicine; nutrition; environmental health; health information; microbiology).

The *National Organisation for Transplants* co-ordinates the extraction and transportation of organs and is responsible for the selection of recipient patients.

The *Spanish Pharmaceutical Agency* oversees the quality, safety and clinical efficacy of pharmaceuticals and authorises the commercial registration of new drugs.

Other subordinate agencies are the *National Institute of Consumer Affairs*, the *Spanish Food Safety Agency*, the *Government Delegation for the National Plan on Drugs*, the *Agency for the Quality of the NHS*, the *Institute of Health Management (INGESA)* and the *National Health System Observatory*.

Other central government ministries

The *Ministry of Labour and Social Affairs* is involved in organising payment of civil servants. Most health professionals within the NHS are civil servants.⁶⁴ Until 2003, the ministry was also involved in defining the overall structure of the social security system and the health care benefits package. Its role was reduced by the 2001 Act on the Financing System of the Autonomous Communities and the 2003 Cohesion and Quality of the NHS Act.

The *Ministry of Economy and Finance* prepares the annual general budget bill and is responsible for regulating private health insurance and pharmaceutical pricing. It is also involved in negotiating reforms and strategies with the regions and it does so through the *National Council on Financial and Fiscal Policy (Consejo de Política Fiscal y Financiera de las Comunidades Autonomas)*. The Ministry administrates several programmes that aim to compensate for the uneven distribution of funds across regions. However, their impact on reducing inequalities as they relate to access to health care has been limited and it is expected that the Ministry will engage further in negotiating additional arrangements for financial compensation with regional governments.

The *Ministry of Public Administration* regulates most aspects of recruitment and employment of health personnel and, more generally, civil servants.

ⁿ Some of the autonomous communities have recently begun to develop separate regional agencies for health technology assessment.

Other ministries involved in the regulation or organisation of specific aspects of health care are the *Ministry of Education and Science*, the *Ministry of the Environment*, the *Ministry of Internal Affairs*, the *Ministry of Defence* and the Ministry of Justice.⁶⁴

Regional authorities

The *Interregional Council of the NHS (Consejo Interterritorial del Sistema Nacional de Salud, CISNS)* coordinates regional health policies. The CISNS is mainly formed by representatives from the regions with members of the central government participating as appropriate. The CISNS thus provides a forum for discussion and negotiation of health policies between the regions and central government.⁶⁷ The negotiation mechanism involves several tiers of regional health administration. For example, topics of national relevance are discussed at the ministerial level, while issues relating to the actual management of health services are normally discussed at the level of management organisations. The formal status of most agreements reached by the CISNS is that of recommendations, though some are binding covenants.⁶⁸

The role of the CISNS was strengthened by the 2003 Cohesion and Quality Act, which extended its scope to issues relating to policy co-ordination, co-operation, service planning and evaluation.⁶⁷ Most of the new functions involve high-level negotiations, e.g. agreements on the core (national) benefits package and the mechanisms in place to expand the package at regional level.

Regional governments are responsible for organising and planning services provided in the NHS within their territory. Regions own and operate health care facilities and organise the entire range of health services almost autonomously. They also determine the extent to which responsibilities in regional health systems are further decentralised. Regional governments (and regional parliaments) can develop legislation for almost the entire public sector. If a regional law is considered to be in conflict with national legislation the central government can challenge the law through appealing to the appropriate high court.

Tensions are common between the centre and the regions as well as between regions, mainly reflecting the uneven distribution of political power across regions. This has been addressed by the 2001 Act on the Financing System of the Autonomous Communities, which aimed to harmonise the status of regions through the introduction of a new general financing scheme and by devolving responsibility for health care organisation and management to regions governed by INSALUD⁶⁴ and by other legislation mentioned above.

Regional Health Authorities/Regional Ministries of Health (Consejerías) are responsible for determining regional health policies and for ensuring that regional health services operate appropriately. Regional authorities/Ministries of Health usually comprise a regional minister (where appropriate), one or more appointed deputies, a secretariat supported by general directorates and a network of provincial health offices.

Health services management organisations (HSMO) (Servicios Regionales de Salud) organise regional services provision within the health care budget received from the regional Ministry of Health/health authority. Arrangements to separate purchaser and provider organisations differ between regions.

Local authorities

Local governments are responsible for basic public health functions. Historically, local governments were in charge of running and financing local health care networks but their role was reduced when responsibility for organising health services was shifted to the regions in the 1970s. Local governments have retained the right to participate in decision making at local level, where they usually have an advisory function, and they mainly do so through their participation in regional health authorities.

Health areas are responsible for managing primary and secondary health care facilities and run benefits and health service programmes within a geographical area covering 200,000 to 250,000 inhabitants. Although health areas were introduced by law, they do not exist in all regions.

Basic health zones are organised around a single primary care team (EAP), covering a population of between 5,000 and 25,000. They are responsible for delivering health services including prevention, health promotion and community care activities. The head of an EAP is accountable to the manager of the health area and to the regional government.

Other stakeholders

- Organisation of Medical Colleges (OMC);
- Medical trade unions (CESM), Nursing Association (SATSE), socialist (UGT) and communist (CCOO) trade union;
- Federation of Associations for the Defence of the Public Health Care System (FADSP);
- Spanish Society of Family and Community Medicine (SEMFYC);
- Spanish Society for Public Health and Health Management (*Sociedad Espanola de Salud Publica y Administracion Sanitaria*, SESPAS);
- National Council of Medical Specialties.

These actors are usually consulted (by the Ministry of Health) on draft proposals. Their role is limited, partly reflecting fragmented interests (e.g. along ideological lines), and they only occasionally influence health policy.⁶²

5.2 Key governance functions

Definition of the benefits package

Residents' entitlements to health care services are defined in the 2003 Cohesion and Quality Act. The Act was passed by parliament, i.e. it has the highest legal status in the Spanish legislative hierarchy.⁶⁹ The Act specifies the general entitlement to health care set out in the constitution and a previous definition of benefits set out in the 1995 Royal Decree 63/1995, which identified broad areas of health care services that regional health systems had to cover.

The 2003 Act also identifies a number of areas for which benefits have to be agreed on by the CISNS.⁶⁴ The list of benefits approved by Royal Decree in December 2006 following an agreement on further additions/de-listings/specifications between the regions represented in the CISNS. The 2006 decree also established mechanisms for the inclusion of additional benefits that are added to the benefits package by the regions.⁷⁰ Within the CISNS the role of the MoH is limited to co-ordinating and participating in the negotiations between regional governments and making suggestions.

Regions are allowed to add extra services to the nationally defined core benefits package if they are prepared to finance them through their own resources.

Overall health care financing

(a) Collection of funds

Health care is mainly financed through taxes raised at central and regional levels. The General Health Care Act of 1986 replaced the previous system that was mainly based on social health insurance by taxation. This decision was taken by central government and confirmed by parliamentary vote.⁶⁴ In 2001 (following the Act on the Financing of the Autonomous Communities 21/2001) the central government devolved further tax-raising powers to the regions and the role of the regions in financing health care has subsequently increased.⁶⁴ The level of statutory user charges (for pharmaceuticals) is set by the central Ministry of Health within a framework established by the Ministry of Finance.⁷¹

(b) Allocation of funding

The Act 21/2001 also restructured the transfer of funds from the centre to the regions. The allocation of funds from the centre is negotiated annually between the central government and the regional governments. The new allocation model was approved by the National Council of Financial and Fiscal Policy before being implemented at central level. The Act stipulates the rules for calculating a minimum level of expenditure that regions are required to spend on health services.⁶⁴

The tax allowance from the centre is further supplemented by several other public funds aiming to compensate for regional differences in revenue and need. These funds are allocated according to a formula set out in the Act 21/2001. Two funds address general economic imbalances and are not specific to health care: the Interterritorial Compensation Fund subsidises investment projects and the Sufficiency Fund can be used to cover gaps in tax funding. In addition, two funds have been created specifically to address inequalities in health care: the Temporary Disability Savings Programme Fund allocates additional funds according to regional population size and the Health Care Cohesion Fund subsidises health care expenditure for residents seeking care abroad and for citizens from other EU countries seeking care in Spain.

(c) Budget setting

Regional governments are free to allocate the funds they receive from the central government as they wish, so long as they spend a legally-stipulated minimum amount on health care. Regional ministries of health typically set the overall budget for publicly-financed health care in collaboration with regional ministries of finance and allocate funds by sector. The health budget is managed by regional health

services management organisations (HSMOs). These organisations usually have little influence on the size of the overall budget.

Price setting

(a) Pharmaceuticals

Prices for pharmaceuticals (including the level of reimbursement for drugs subsidised under the reference pricing scheme) are set by the Ministry of Economy and Finance in collaboration with the MoH within the Interministerial Commission on Prices.

(b) Services in ambulatory and hospital care

Services provided in public hospitals are mainly funded through global budgets; services in ambulatory (primary) care mainly through capitation. Budgets for ambulatory care (including capitation fees) and hospital care are determined by regional ministries of health (see above). HSMOs manage the budget for the regional NHS and negotiate annual budgets with public hospitals.^o Deficits incurred by public hospitals are usually covered by the public purse.

Prices for public services provided in private hospitals are negotiated directly (collectively or individually) between private providers and the regional purchasing authority.

(c) Salaries of nurses and doctors

The Ministry of Public Administration determines the basic salary of physicians and other health personnel working in the NHS who have a status similar to civil servants. Additional salary components vary among regions and are negotiated between regional ministries of health / HSMOs and the respective union and/or professional organisation.

Salaries of health professionals working in foundation hospitals (with a status similar to NHS foundation trusts in England) or in private hospitals are negotiated between the individual professional and his/her employer. However, unions and professional organisations have increasingly become involved in defining contractual arrangements between employers and employer, particularly for foundation hospitals.

The level of income of nurses and doctors varies substantially between regions.

5.3 Government scope of action

As noted above, responsibilities for the functioning of the health care system rest mainly with the governments of the 17 regions. The scope of action for the central Ministry of Health is very limited and is mainly restricted to preparing national legislation, which is then passed by parliament, and by participating in negotiations between the regions through the CISNS. The Ministry's role reflects, broadly, the responsibility of the central government for ensuring access to health care guaranteed by the constitution. However, its role is generally limited to developing

^o Although most regions have introduced Diagnosis-related groups (DRGs) in the hospital sector DRGs are mainly used to enhance the transparency of hospital finances ('shadow accounting') rather than as a method of funding.

legislation that is then passed by parliament, as in the case of the definition of the core benefits package and the development of an allocation formula for the distribution of funds from the centre to the regions.^p

Apart from the above examples most key governance functions are held by regional governments. Access to in-vitro fertilisation, major financial investments (e.g. into new hospital developments), patient safety (e.g. hospital acquired infections) and failure of individual providers (including financial deficits) typically fall under the remit of the regions. Citizens may challenge a decision of a regional or central government in court. However, court decisions tend to be in favour of the government.

Government intervention, if at all, is typically through participation in the CISNS in which its main role is to co-ordinate activities and mediate negotiations between the regions.

Issues in which the central government may get involved include:

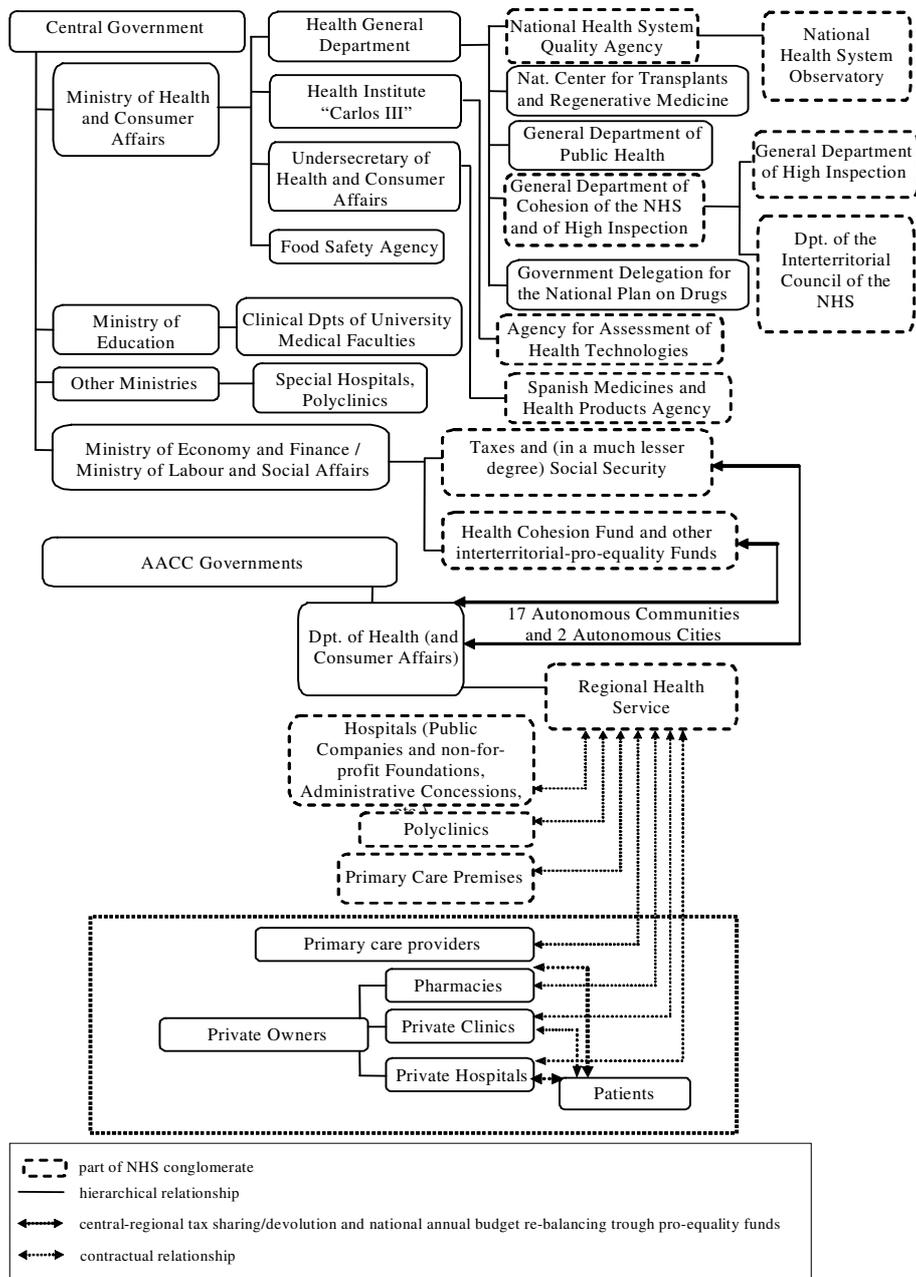
- *Regional overspending:* In theory, the central government could hold a regional government to account if it overruns its budget. In practice, however, in view of strong regional autonomy in matters of finance and organisation of public services, the central government usually covers the financial deficits of the regions to avoid political confrontation.
- *Public health crises of national importance:* Examples of public health issues with a national dimension have been numerous in recent years and have included heat waves, environmental disasters (e.g. the Prestige ship oil spill), health concerns associated with mobile phone masts and potential epidemic outbreaks (SARS, avian influenza). In these cases, the central government has mainly assumed the role of a co-ordinator of regional activities and it appears to have fulfilled this role 'reasonably well'.

In contrast, cases of individual provider failure usually remain contained at the regional level, even if they attract media attention across regions. Cases of professional malpractice are dealt with by the courts as illustrated by the case of an anaesthesiologist in Valencia who infected several hundred patients with Hepatitis C.⁷³ Another equally publicised case, in which a hospital in Madrid was criticised for its use of sedatives on patients with end-stage cancer, was attended to at the regional level.⁷⁴

Reflecting the devolved nature of responsibility for health care, the health minister of the central government is less exposed to public criticism in cases of health system failure than perhaps their regional (and some of their international) counterparts. Presumably, a health minister would have to fail to co-ordinate regional responses to a national public health crisis in order to attract any severe criticism; no such case has been reported during the 30 years of existence of the Spanish health system.

^p Some authors have argued that the mechanism for compensating regional inequalities is insufficient and that the central government lacks the executive power to respond to inequalities adequately. [72].

Figure 5.2 Organisation of the Spanish health system⁶⁴



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