

News and Views

Supervision by the Dutch Healthcare Inspectorate

F.A.G. Hout^{*,a}, E.D. Nienhuis^b, P.B.M. Robben^c, B.J.M. Frederiks^d and J. Legemaate^e

^a Researcher/Adviser to the Healthcare Inspectorate, The Hague, The Netherlands

^b Adviser to the Healthcare Inspectorate, Utrecht, The Netherlands

^c Director, Healthcare Inspectorate, Knowledge Centre, Utrecht, The Netherlands
Professor, Erasmus University Institute of Healthcare Policy & Management,
Rotterdam, The Netherlands

^d University Lecturer in Health Law, Department of Social Medicine,
VU University Medical Centre, EMGO, Amsterdam, The Netherlands

^e Professor of Law, Department of Social Medicine,
VU University Medical Centre, EMGO, Amsterdam, The Netherlands

Abstract

The Dutch Healthcare Inspectorate's (*Inspectie voor de Gezondheidszorg*) supervisory activities are based on proportional use of the instruments. The primary instruments it uses are advice and encouragement. If these do not achieve the desired result, it can implement corrective action by, for example, enhancing its supervision or through agreements limiting the ability to practise a profession. Recourse to disciplinary or administrative measures can be sought, if necessary. There is a tendency to use statutory instruments, which means greater equality before the law and greater legal certainty. It is important in this respect for the Inspectorate to make its considerations more uniform, transparent and predictable.

Keywords

supervision; Dutch Healthcare Inspectorate; disciplinary law; administrative law; advice; proportionality; enforcement framework

1. Introduction

The tasks and public law powers of the Dutch Public Health Supervisory Service are statutorily laid down in Article 36 of the Public Health Act [*Gezondheidswet*] of 1956. The Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*, 'the Inspectorate') is part of the Supervisory Service and reports to the Ministry of Health, Welfare and Sport.¹ The supervision performed by the Inspectorate has

* Currently: Researcher, Knowledge Centre of Trajecton Corporation, Boshcoord, The Netherlands.

¹ Article 1:1, opening words and subsection (a) of the State Supervision of Public Health Decree [*Besluit Staatstoezicht op de Volksgezondheid*].

a very wide scope, ranging from supervising the professions and institutions operating in the healthcare sector to combating and preventing illnesses, promoting health and mental healthcare, pharmaceuticals (including narcotics), the blood transfusion service and medical devices and equipment. Its activities also include ensuring compliance with 23 items of legislation and other legal provisions, such as European rules and international treaties, in an extremely wide-ranging sector comprising some 800,000 healthcare professionals and 3000 healthcare institutions.²

Although the Inspectorate, as the enforcement organisation, contributes to the quality of care, it emphasises, in accordance with the statutory provisions, that those with primary responsibility for quality in the healthcare system are the healthcare providers themselves. It continually seeks to maintain a balance between results and the efforts needed to achieve a safer healthcare system.³ These efforts involve encouraging institutions and professional practitioners to provide their care services responsibly, to identify and deal with abuses and to comply with legislation and regulations.⁴ Reports received from citizens and healthcare providers on healthcare institutions, healthcare practitioners, medical aids and equipment constitute an important source of information for the Inspectorate's supervisory activities. The instruments that the Inspectorate applies in response to these reports are used proportionally. The first instruments to be applied are usually measures for which no provision is made in law and commonly involve persuasion, enhanced supervision or agreements in writing. Where necessary, however, intervention will be more rigorous and involve various formal or statutory instruments.

The Guideline for Transparent Enforcement [*Richtlijn voor transparante handhaving*]⁵ details the Inspectorate's appraisal methods and choice of measures,⁵ while also referring to the principle of proportionality. The latter is taken to mean that the instruments applied will not go further than is needed to achieve the desired objective. In other words, the principle of a soft approach where possible and a hard approach where necessary. The Inspectorate's long-term policy plan for 2008-2011 devotes specific attention to innovation in methods of enforcement and research into the effectiveness of supervision in the form of programme-based evaluation research.⁶ One of the projects within the evaluation programme involved research by the VU University Medical Centre's EMGO⁺ Institute for Health and Care Research into the way in which the Inspectorate handles its right to submit disciplinary complaints.⁷ The Institute's

² *Policy plan 2008-2011. Voor gerechtvaardigd vertrouwen in verantwoorde zorg* (The Hague: Healthcare Inspectorate, 2007).

³ *Work plan 2009. Handhaven met effect* (Utrecht: Healthcare Inspectorate, 2008).

⁴ *Work plan 2007. Risico's eerst*, (The Hague: Healthcare Inspectorate, 2006).

⁵ Enforcement framework of the Inspectorate. *Richtlijn voor transparante handhaving* (The Hague: Healthcare Inspectorate, 2008).

⁶ See *supra* note 2.

⁷ E. Hout, E. Nienhuis, B. Frederiks, J. Legemaate, *De Inspectie voor de Gezondheidszorg en het tuchtrecht*, (Amsterdam: VU University, EMGO, Amsterdam, 2009).

research examined the use of statutory instruments and instruments for which no provision is made in law. This article discusses that research and examines the following research questions:

1. What forms of supervision does the Inspectorate apply?
2. What formal instruments and instruments for which no provision is made in law are available to the Inspectorate?
3. How often are these various instruments used, what do they involve and what are the reasons for deciding to apply them?

The primary focus in answering the first and second questions was on legislation, Parliamentary papers and the Inspectorate's policy documents. File investigations were conducted to establish how often regulatory instruments are used and the reasons for this, based on data from internal incident recording. Sources outside the Inspectorate were also used, including results of internet searches. The research into the use of formal instruments examined information covering a six-year period (2002-2007), while an analysis of incoming reports received in 2007 was used to provide an indication of the use of measures for which no provision is made in law.

2. Results

2.1. Legislative Framework

The tasks assigned to the Inspectorate under the Public Health Act include ensuring compliance with and identifying violations of the provisions in or pursuant to statutory regulations in the field of public health. This currently involves a total of 23 items of legislation. As far as the Inspectorate's supervisory responsibilities are concerned, the main items of legislation that are of importance are the Care Institutions Quality Act [*Kwaliteitswet zorginstellingen*] — in the case of institutions — and the Individual Healthcare Professions Act [*Wet op de Beroepen in de Individuele Gezondheidszorg*] — in the case of individual practitioners. In addition to the administrative law powers granted to the Inspectorate under this specific legislation, most of which are discussed in this article, the Inspectorate also has various general powers under the General Administrative Law Act [*Algemene wet bestuursrecht*] that are granted to all those responsible for supervision under or pursuant to statutory provisions.⁸ These latter powers include the right to enter dwellings without the occupant's consent, the right to demand information and inspect commercial information and documents, the

⁸) P.J.J. van Buuren *et al*, *Tekst en Commentaar: Algemene wet bestuursrecht* (Deventer: Kluwer, 2009): on chapter 5.2, General Administrative Law Act.

right to inspect, survey and take samples of goods and the right to inspect means of transport.⁹

2.2. *Methods of Supervision*

The supervision performed by the Inspectorate is based on legislation and regulations. In those situations in which the legislator has set only general standards in legislation, the Inspectorate bases its supervision, wherever possible, on 'field norms' set by healthcare providers and professional groups themselves. If no 'field norms' are available in a specific area, the Inspectorate will set specific supervisory norms for itself.¹⁰ The Inspectorate performs its supervision in three ways: phased supervision, theme-based supervision and supervision of incidents.

Phased supervision is designed to provide insight into the general level of care provided and should be regarded as preventive supervision. Its primary objective is to seek to limit risk, which is why it mainly focuses on those areas of the healthcare sector where risks are greatest.¹¹ Phased supervision is performed in three phases. The first of these involves assessing the risks of a lack of safety and of shortcomings in quality, based on an analysis of the quality control information ('indicators') supplied by healthcare providers. The second phase comprises inspection visits to healthcare providers where there is a risk of a lack of safety and of shortcomings in quality. The inspector will then assess the need for measures to be taken by the healthcare providers and stipulate the timeframe for implementing these measures. The third and final phase is when the Inspectorate will, when necessary, intervene.¹²

Theme-based supervision involves investigating a single aspect of the care provided at a national or regional level. This supervision is also a form of preventive supervision, in which situations requiring intervention may also arise.

Incident supervision can be regarded as repressive supervision and is performed in response to signals or reports of serious problems or emergencies. In principle, reports are submitted voluntarily, although in some cases there is a statutory reporting duty. The Care Institutions Quality Act, for example, requires institutions to report emergencies and cases of sexual abuse immediately. An emergency is any unintended or unexpected event relating to the quality of care and that has resulted in the death of or serious consequences for a patient or client of the institution.¹³ The Reporting Guideline outlines how reports have to be dealt with and which reports have to be investigated. Incident supervision regularly results in intervention.

⁹ Articles 5:15, 5:16, 5:17 and 5:18, General Administrative Law Act.

¹⁰ See *supra* note 5.

¹¹ *Bulletin. Toezicht als borg voor kwaliteit van zorg. De inspectie voor de Gezondheidszorg als onafhankelijk toezichthouder in het nieuwe zorgstelsel* (The Hague: Healthcare Inspectorate, 2003).

¹² Guideline for Phased Supervision (Utrecht: Healthcare Inspectorate, 2008).

¹³ J. Legemaate, I. Christiaans-Dingelhoff, R.M.S. Doppegieter, R.P. de Rooze, *Veilig incident melden. Context en randvoorwaarden* (Houten: Bohn Stafleu van Loghum, 2007).

2.3. *Types of Measures, Instruments and Assessment*

The Inspectorate has a range of different measures and associated instruments at its disposal. Usually it opts to use measures for which no provision is made in law. Where necessary, the Inspectorate can apply the formal measures at its disposal, as provided for in law. The various statutory measures comprise criminal, disciplinary and administrative measures, while the measures for which no provision is made in law comprise corrective measures and advice and encouragement. If an offence is suspected of having been committed, the Inspectorate can instigate criminal investigations or report the matter to the Public Prosecution Service, and it is up to the Public Prosecution Service to decide whether to bring a prosecution. The statutory measures available to the Inspectorate are principally in the spheres of disciplinary and administrative law. The disciplinary instruments available include the right to lodge a disciplinary complaint and to bring a professional before the Medical Supervision Board [College van Medisch Toezicht], while examples of administrative measures include the right to issue a compliance order and to initiate instructive measures. The corrective measures available include enhanced supervision and demanding preparation of an action plan to achieve the required improvements.¹⁴ Although agreements on restricting the ability to practise are not specified as such in the enforcement framework, they, too, are an example of a corrective measure, while advice and encouragement include seeking to persuade and incentivise institutions and individuals and convincing them of the need to improve.

When deciding which measure is most appropriate in specific circumstances and thus most likely to improve the quality of healthcare, the Inspectorate assesses the seriousness of the situation and the likelihood of repetition. Insight into the seriousness of the situation is obtained by combining information on the type of problem (the five Ds of dissatisfaction, discomfort, disease, disability and death) with information on the numbers of people potentially at risk. The criteria considered when assessing the likelihood of repetition include the extent to which the care is organised and structured with a view to quality and safety outcomes and the attitude of the healthcare provider (ignorance, incompetence, non-compliance). Fig. 1 provides an indication of the type of measure employed, based on the seriousness of the situation multiplied by the chance of repetition. This system is designed to provide an operating framework, from which the Inspectorate can choose to diverge, providing reasons for such divergence are given. It is also possible to opt for a lighter or heavier instrument within the type of measure chosen.¹⁵ The Inspectorate recently devised and published an enforcement framework for various formal instruments, as well as for enhanced supervision.¹⁶

¹⁴ See *supra* note 5.

¹⁵ *Ibid.*

¹⁶ Parliamentary Papers I, 2009/10, 31 122 annex J.

Seriousness of situation	Chance of repetition		
	High	Average	Low
High	Disciplinary or criminal	Administrative	Corrective
Average	Administrative	Corrective	Advice and encouragement
Low	Corrective	Advice and encouragement	Advice and encouragement

Figure 1. Indication of type of measure, based on seriousness of situation x chance of repetition.¹⁷

2.4. Description and Use of and Background to Each Type of Instrument

This section provides a description, for each type of instrument, of the measures themselves, the background to them, the way in which and how often they are used. Firstly we examine the remedy of advice and encouragement, and the various corrective measures that can be applied. We looked at the overall use made of these measures, for which no provision is made in law, in 2007. We then examined various disciplinary and administrative measures and the extent to which these statutory instruments were used between 2002 and 2007.

2.4.1. Advice and Encouragement and Corrective Measures

The informal remedies available to the Inspectorate as a means of improving day-to-day activities include using the Inspectorate's own expertise and independence in consultations designed to persuade and convince people and institutions of the need for change.¹⁸ The Inspectorate can reach agreements with a healthcare provider on improving day-to-day activities. These will specify what needs to change and by when.

If advice and encouragement fail to achieve the desired changes, the Inspectorate can seek to avoid using a formal instrument by informing a healthcare provider that it will proceed to apply a formal instrument or, in the case of individual natural persons, to apply measures restricting their ability to practice their profession if the requested changes do not materialise by a specified date. Another example of a corrective measure is the Inspectorate's right to impose enhanced supervision. This is permitted if a warning issued does not result in the desired changes. Enhanced supervision is a stringent form of supervision and represents

¹⁷) In line with *IGZ-Handbavingskader. Richtlijn voor transparante handhaving* (The Hague: Healthcare Inspectorate, 2008).

¹⁸) *Parliamentary Papers II*, 2006/07, 31 122, no. 3.

a final opportunity for healthcare providers to remedy problems within a short period of time, based on an improvement plan. Imposition of enhanced supervision is made public.¹⁹

Analysing the reports from 2007 provided an indication of the extent to which informal measures are used. This is because most reports result in these measures, for which no provision is made in law, being applied. The Inspectorate investigated over half of the incoming reports received (2544/4585; 55%) because they involved actual or suspected structural shortcomings in care, sometimes resulting in serious injuries or death. Other categories of incoming reports related to matters such as suicides and near-incidents, but also to signals and complaints without any structural significance and not involving any serious injuries or death.

In 2007 advice and encouragement were given in over 1500 cases. These cases resulted from the over 4500 incoming reports received by the Inspectorate. Institutions and professional practitioners were given advice on, for example, preparing an improvement plan (on 136 occasions), amending quality control systems (on 222 occasions), on organisational (332 occasions) or personnel (120 occasions) measures and on other measures (481 occasions). On 127 occasions citizens were advised to submit their complaint to a complaints committee. In more cases (over 2200), no advice or encouragement by the Inspectorate was needed. Instead, the professional practitioners or institution themselves initiated improvements in response to the report.

The total number of corrective measures applied is difficult to quantify, not only because until recently agreements restricting the ability to practise a profession were not recorded centrally, but also because no information is recorded on when advice to implement an improvement measure is replaced by a requirement to implement the specific measure because of the advice not being followed up. Enhanced supervision was imposed on six occasions in 2007. Based on an estimation by the Inspectorate, agreements restricting the ability to practise a profession are made on between ten and twenty occasions a year. An examination of questionnaires shows that almost a quarter of the inspectors (25) were involved in such agreements with institutions or professional practitioners during the past year. Of these cases, a total of five involved varying degrees of restrictive agreements (supervision, therapy or a ban), while the others involved applying measures designed to improve a situation rather than imposing professional practice restrictions.²⁰

2.4.2. *Submitting Disciplinary Complaints*

The provisions governing statutory disciplinary proceedings can be found in the Individual Healthcare Professions Act. This legislation is in the public interest

¹⁹⁾ See *supra* note 4.

²⁰⁾ See *supra* note 7.

and designed to ensure the professions covered are practised with due care and expertise. Its primary purpose is to monitor and promote quality. On the one hand it provides the opportunity to impose disciplinary measures, while on the other hand also allowing professional standards to be developed and made explicit.²¹

In the event of acting against the disciplinary norms the Inspectorate — alongside other complainants, incidentally — is authorised to bring disciplinary proceedings against individual natural persons practising in eight professions.^{22, 23} The Inspectorate may ask the disciplinary court to handle a case urgently, while the court can also impose provisional measures on the specific practitioner. The Inspectorate is authorised to appeal against the disciplinary court's ruling. Similarly, providing this is in the public interest, it can also lodge appeals in cases to which it was not in first instance a party.

The disciplinary court can impose the following measures: firstly a formal warning and reprimand. A warning constitutes a professional rebuke, while a reprimand also contains elements of reproach and blame. In the event of more serious misconduct, practitioners may be fined up to €4500, have their registration suspended (or conditionally suspended) for up to a year, have their authority to practise be partially revoked or be permanently removed from the register.

Between 2002 and 2007 regional disciplinary boards handled a total of 117 disciplinary proceedings initiated by the Inspectorate. That means an average of twenty a year, over half of which (58%) involved doctors. Those subject to these proceedings were primarily medical specialists (27%) and general practitioners (15%). Other medical practitioners appearing relatively frequently before disciplinary courts were nurses (21%) and dentists (8%). Around two thirds (65%) of the complaints handled by the Inspectorate were related to accusations of 'insufficient care' or 'incorrect treatment or diagnosis', while 'inappropriate behaviour' also occurred relatively often (19%).

In many (84%) of the cases, the disciplinary court found the complaint to be well-founded, with the principal measures imposed being admonitions, warnings and suspensions (23%, 21% and 21% respectively of all rulings). In around 10% of rulings, registrations were revoked. The Inspectorate appealed against rulings in 17 of the 117 cases, and in over half of these cases (10 of the 17), the appeal resulted in measures or more stringent measures being imposed.

²¹ J. Lucieer, *Inzicht in het Staatstoezicht op de Geestelijke Gezondheidszorg 1841-2005* (Nijmegen: WLP, 2005).

²² The professions are doctor, dentist, pharmacist, health care psychologist, psychotherapist, physiotherapist, midwife and nurse.

²³ Professional practitioners can firstly be subject to disciplinary proceedings in the event of acts or omissions violating the duty of care that they are required to observe, while also being subject to such proceedings in the event of any other act or omission contravening the interests of the proper provision of individual healthcare.

2.4.3. *Referral to the Medical Supervision Board*

The purpose of the Medical Supervision Board is to assess whether a practitioner is fit to practise. The Inspectorate has exclusive powers to make written referrals to the Medical Supervision Board in respect of the eight professions specified earlier. Referrals may be triggered by a practitioner's mental or physical health, alcohol abuse or abuse of any substances referred to in Articles 2 and 3 (exhaustive list) of the Opium Act [*Opiumwet*]. The measures that the Council can impose include ordering practitioners to comply with special conditions, partially revoking practitioners' entitlement to practise or their removal from the register maintained pursuant to the Individual Healthcare Professions Act.²⁴

Between 2002 and 2007 the Medical Supervision Board issued ten rulings in response to referrals by the Inspectorate. On three occasions, the practitioners' names were removed from the register, while in three cases the rulings subjected the individuals to compliance with special conditions. In the other cases, the referrals were dismissed as unfounded after the case had been heard (3x) or withdrawn. The rulings involved eight doctors, one dentist and one nurse. The referrals related to substances covered by the Opium Act (4x), alcohol abuse (2x) or mental fitness to practise (2x). In two cases the referral related to other issues.

2.4.4. *Compliance Order under the Individual Healthcare Professions Act*

The Individual Healthcare Professions Act allows the Inspectorate to serve a written compliance order on people in any of the eight professions specified earlier, as well as on those practising a profession for which training is governed by or approved under the Act, such as pharmacists' assistants, dental hygienists and occupational therapists. This right applies to practitioners not working within an institution, but independently and who do not meet the duty of care. In other words, those failing to provide care of a good level, in an effective and patient-oriented manner and in line with the real needs of the patient.²⁵ How the concept of the duty of care is interpreted is up to the healthcare providers themselves, although there are various reference points to guide them. Practitioners must comply with the order within the period specified. In the event of the order being contravened, the Minister of Health, Welfare and Sport can use administrative enforcement or impose an incremental penalty.

Between 2002 and 2007 the Inspectorate imposed compliance orders under the Individual Healthcare Professions Act on eleven occasions. These orders were served on six general practitioners and three dentists because of failure to operate satisfactory locum arrangements (3x), abuse of substances covered by the Opium Act (2x), alcohol abuse (1x), irresponsible provision of care as a result of action contravening the law (1x), unauthorised use of a protected title (1x) and a refusal

²⁴ *Parliamentary Papers II*, 1985/86, 19 522, no. 3, p. 82.

²⁵ Article 2, Care Institutions Quality Act.

to be vaccinated against hepatitis B (1x). Under the compliance orders, those concerned were required to discontinue their practice or cease practising their profession (4x) or to make locum arrangements, subject to an incremental penalty (3x) or were banned from using the title of general practitioner (1x). In three cases, Medical Supervision Board proceedings were instigated at the same time as the compliance order or later, while in two cases a disciplinary complaint was filed at the same time as the compliance order. On three occasions, the proceedings resulted in a practitioner being removed from the register.

2.4.5. *Advice/request for Instructions and Compliance Order under Care Institutions Quality Act ('Quality Act')*

The Care Institutions Quality Act [*Kwaliteitswet*] allows the Inspectorate to take action against institutions failing to meet their duty of care. The Inspectorate can advise the Minister of Health, Welfare and Sport to issue written instructions specifying the ways in which the provider fails to comply with the duty of care, as well as listing the measures to be taken and the period within which these have to be implemented.²⁶

If the matter is urgent, the Inspectorate itself can also even serve a written compliance order on a healthcare institution. Such an order can be issued for a maximum of seven days and can be extended by the minister if this is required in order to achieve the objective of the order and the extension follows immediately after the initial compliance order issued by the Inspectorate.²⁷ If the healthcare institution contravenes the compliance order or the instructions served under the Quality Act, the Minister of Health, Welfare and Sport can proceed to administrative enforcement by, for example, closing all or part of the institution or imposing an incremental penalty.

At the recommendation of the Inspectorate, the Minister imposed a total of seven written instructions on six institutions in the period 2002-2007. Three of these were in respect of four mental healthcare institutions (one of these was a joint venture between two institutions), while three related to a single hospital and one to an ambulance service. The reasons for these instructions were administrative problems (4x) and failure to provide the required quality of care (1x). In two cases, the reasons for and contents of the instructions could not be established because the file had been mislaid within the Inspectorate.

Between 2002 and 2007 the Inspectorate made use of its authorisation to impose compliance orders under the Quality Act on six occasions, involving five institutions. These orders were served on three hospitals and two private clinics. One hospital was served with two orders, after three earlier instructions had

²⁶ Article 7, Care Institutions Quality Act.

²⁷ *The Care Institutions Quality Act. Procedure bevel, aanwijzing en bestuurdwang* (The Hague: Ministry of Health, Welfare and Sport, 2002).

failed to produce the desired effect. In the cases of the private clinics, conditions on the work floor were essentially not such that a responsible level of care could be assured, while the reasons for the orders served on the hospitals related to internal conflicts, insufficient coordination or administrative problems. The compliance orders resulted in the closure of all or part of the institution (3x), imposition of an admissions ban (2x) and a ban on heart operations (1x).

2.5. *Overview of Use of the Various Instruments*

Table 1 shows the extent to which the Inspectorate used the various regulatory instruments in 2002-2007 and in 2007. The extent to which formal measures were used was limited, certainly in comparison to the numbers of occasions on which informal measures were used. It should be noted, however, that informal measures can be directed against any individual or institution in the healthcare sector, whereas the formal measures can be applied only in respect of individuals in specific professions (a compliance order under the Individual Healthcare Professions Act or rulings by the Medical Supervision Board or a disciplinary tribunal) or in respect of specific healthcare institutions (compliance orders or instructions under the Quality Act).

3. Conclusion

In practice the Inspectorate does not use the formal instruments at its disposal very often. For many years it has operated on the principle of a 'soft approach where possible and a hard approach where necessary',²⁸ largely relying on

Table 1. Inspectorate's use of regulatory instruments in 2002-2007 and 2007

Measure	2002-2007	2007
Rulings by disciplinary tribunal of the first instance	117	9
Rulings by Medical Supervision Board	10	0
Compliance order under Individual Healthcare Professions Act	11	1
Compliance order under Quality Act	6	0
Instructions under Quality Act*	7	0
Informal measures	Not known	Over 1500

* Minister of Health, Welfare and Sport is authorised to refer, at the Inspectorate's request.

²⁸⁾ See *supra* note 5.

authority and trust. Much of the Inspectorate's work consists of consultations and giving encouragement and advice. If its supervisory activities identify problems with only limited consequences, the Inspectorate will contact the healthcare institutions or professional practitioners and use the various informal measures at its disposal. In this way it can often avoid having to impose administrative sanctions or the need for disciplinary or criminal proceedings.

In 2007, the over 4500 incoming reports received by the Inspectorate resulted in more than 1500 informal reactions. A special category within the informal measures is the ability to agree restrictions on the right to practise a profession as this gives rise to certain legal questions. The advantage of such agreements is that they can be established within a relatively short period of time and that the Inspectorate itself can determine what the agreements contain. The disadvantages are that only the Inspectorate and the practitioner in question know of the existence of the agreement, while the agreement provides no opportunities as such to enforce the measure if the practitioner fails to comply and, in the case of far-reaching agreements (such as agreements by practitioners to stop working or to remove their names from the medical register), the safeguards in place to protect practitioners' legal position are inadequate.²⁹

The Healthcare Inspectorate is certainly not alone in its clear preference for using the informal remedies available to it. Back in 1964 the public administrator Brasz found that regulators chose to use their formal powers in only 10-15% of cases,³⁰ with a survey among 28 Dutch state inspectorates in the late 1980s confirming this view.³¹ Supervisors are not very effective if they seek recourse to formal remedies in significantly more than 10% of cases, as greater use of formal instruments does not result in better supervision.^{32, 33} Formal remedies and repressive action are time-consuming and can result in undesired side effects, such as creating mistrust among professionals and frustrating the process of self-regulation. They can also lead to healthcare providers becoming reticent in their dealings with the Inspectorate and to information provided to the Inspectorate being distorted.

The Inspectorate sees repressive intervention, involving formal instruments, as *ultimum remedium*. Much of the supervision performed in the Netherlands, also in sectors other than the healthcare sector, is based on phased, proportional use of informal and formal remedies, with the formal instruments primarily

²⁹ J. Legemaate, F.A.G. Hout, B.J.M. Frederiks, P.B.M. Robben, 'Het maken van beroepsbeperkende afspraken door de inspectie', (1) *Tijdschrift voor Gezondheidsrecht* (2010) 17-23.

³⁰ H.A. Brazs, *Toezicht op gemeentebesturen. Serie bestuurskundige bouwstenen, no. 1 ed.* (Alphen aan den Rijn: N. Samson NV, 1964).

³¹ Report by the Netherlands Court of Audit on 1989. The Hague: Lower House of Parliament, session year 1989-1990, 21 481, nos. 1-2; 1990.

³² J. Braithwaite, T. Makkai, V. Braithwaite, *Regulating Aged Care. Ritualism and the New Pyramid* (Cheltenham: Edward Elgar, 2007).

³³ J. de Ridder, *Een goede raad voor toezicht*. Oration (The Hague: Boom Juridische Uitgevers, 2004).

being viewed as the stick in a 'carrot and stick approach'. It is certainly not always necessary to apply a formal remedy. Indeed, in its 2007 annual report, the Inspectorate stated that it was also able to achieve its objectives by persuading, prevailing on and reaching agreements with parties rather than by seeking recourse to disciplinary action. It also stated that handling a disciplinary complaint was labour-intensive and an activity for which the Inspectorate had insufficient capacity.³⁴

From the second half of the 1990s onwards both the political world and the general public started expecting the Inspectorate to respond more stringently to cases of sub-standard care and serious events in the sector.³⁵ Institutions and professionals meanwhile often see the regulator as being too severe and too quick to seek recourse to formal remedies, with the result that they respond defensively and see supervision as an administrative burden. This means the Inspectorate has to navigate a course between these two opposing interests, and a tendency for the Inspectorate to make more explicit and more frequent use of formal instruments is now being seen.³⁶

The increased transparency of supervision and the greater use now being made of formal remedies also mean institutions and professionals demanding more in terms of equality before the law and legal certainty. Although the Inspectorate's earlier argument that it has too little capacity will always in practice be an issue, it should not be the factor determining which of the various instruments to apply as accepting lack of capacity as a reason for not taking action will not serve to increase equality before the law and legal certainty and so will undermine confidence in the Inspectorate. The role that the availability of human resources plays in deciding on the use of formal instruments should be made explicit, as well as being documented and communicated to the outside world.

The investigation into the way in which the Inspectorate uses its powers to lodge disciplinary complaints highlighted a number of internal problems. The policy rules, for example, are not generally known within the Inspectorate. Only one quarter of inspectors have experience of submitting disciplinary cases, while the extent of the others' experience is not evenly spread. The reasons for this include differences in the way that decisions are taken on whether to instigate disciplinary proceedings, and these differences mean that, despite various consultations designed to monitor and align positions, decisions are essentially taken individually. In addition, too little use is made of existing experience of applying disciplinary remedies, while case features and backgrounds and the considerations influencing decisions are either not documented or are inadequately

³⁴ Annual report 2007 (The Hague: Healthcare Inspectorate, 2008).

³⁵ *Ruimte en rekenschap voor zorg en ondersteuning* (The Hague: Ministry of Health, Welfare and Sport, 2009).

³⁶ See *supra* note 5.

documented in internal registration systems.³⁷ There is no reason to assume that the various problems referred to here arise less frequently in situations where other instruments are used. Other formal instruments are used even less, and other research shows there to be differences in the way inspectors assess situations.³⁸ As far as the clarity and consistency of policy rules are concerned, Inspectorate employees' knowledge of internal policy, the uniformity in exercising the powers to use the various instruments and the quality of the information recorded within the Inspectorate certainly need improving. At a time when more stringent supervision is being demanded, improvements in these respects are important, both from a perspective of equality before the law and legal certainty for those subject to the Inspectorate's supervision and also for the effectiveness of the supervision and, therefore, the quality of care provided. By detailing and publishing an enforcement framework for its various instruments the Inspectorate has taken a first, significant step towards making its work more uniform, transparent and predictable.

³⁷⁾ See *supra* note 7.

³⁸⁾ S.M. Tuijn, E.J.G. Janssens, H. van den Bergh, P.B.M. Robben, 'Het ene oordeel is het andere niet. Kwantitatieve analyse van de variatie bij IGZ-inspecteurs', *Nederlands Tijdschrift voor Geneeskunde* (2009) 322-326.