Evaluation of the Health Care Market Regulation Act

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Summary and Recommendations

Introduction

On 1 October 2006, the Health Care Market Regulation Act (Wmg) took effect. According to the explanatory memorandum, the Act contributes to changes in the Dutch health care system, permitting more room for consumer choice and competion among health care providers and health insurers. The Wmg contains regulations designed to arrive at an effective system of appropriate health care, to control the growth of health care cost and to protect and promote the position of consumers[1]. This evaluation focuses on the four more operational aims of the Wmg[2].

The aims of the legislation are that:

1. Where possible, market forces are introduced and maintained.
2. Where necessary, the government will regulate prices and performance.
3. Health care providers and health insurers will provide patients and policyholders with sound information on which to base decisions regarding which health care provider to choose and which health insurer and insurance policy are best for them.
4. There should be cohesion in the regulation and supervision of the health care markets.

[1] Preamble to the Wmg
[2] Parliamentary reports II 2004-2005, 30 186, no.3 (Explanatory Memorandum)

In order to realise each of these aims, the Wmg has various instruments at its disposal. In this evaluative report we analyse whether and how these instruments have been employed and whether they do indeed contribute to achieving the above aims. We also seek to identify any obstacles in this respect, and we put forward possible solutions to removing the obstacles. In this report we focus mainly on the new instruments and the new situation that has arisen through the introduction of more room for competition in health care. Besides these, the Wmg contains many pre-existing regulations and arrangements dealing with the functioning of healthcare. These regulations, e.g. focussing on tarrifs, are left outside the current evaluation.

The identified obstacles and the solutions proposed should be seen against the background of a relatively smooth introduction of the Wmg. The problems concerning the new instruments or existing instruments in the new free market situation have been explicitly described as *possible* obstacles, for which nevertheless there are also empirical indicators that they do arise. This is because to date, there has sometimes been only very limited experience with the application of this set of instruments. The proposed solutions are suggestions that require further analysis and elaboration in terms of their feasibility, expected efficacy and possible unintended effects.

It remains imperative to monitor the developments and conduct scientific analysis of the underlying mechanisms to see whether the identified obstacles do indeed become more problematic over time and to monitor the emergence of other obstacles.

Because of the relative short time since implementation of the Wmg, this evaluation focuses primarily on the instruments and not on the question whether the inherent goals are being reached. It is also not concerned with the question as to whether more competition in health care is desirable or not. The Wmg can be used both to enable competition and to tighten price and supply regulation in health care markets.

1 The set of instruments for creating and monitoring markets

The Wmg contains two important new instruments that are intended to contribute to introducing competition to markets where scope for competition has been created: the competence of the Dutch Health Care Authority (NZa) to impose specific obligations on those health care providers or health insurers that have significant market power (SMP) within a market segment; and the competence of the NZa to impose generic obligations on all health care providers and/ or health insurers in a market segment, in order to remove general, lasting obstacles to effective competition.

Because scarcely any use has been made of the new instruments for creating and maintaining competition no definitive conclusions about their effectiveness can be drawn. Nonetheless, a number of obstacles have been identified on the basis of an analysis of the two instruments.

Possible Obstacles

1 There is a certain conflict between monitoring a macro budget on the one hand and introducing more competition on the other hand. This tension arises from the desire to provide the best possible care for all as against the desire to manage costs at

macro level. In regulated areas of health care, the instruments for intervening in prices in order to monitor the macro budget are in place, as is illustrated in the case of orthodontics (Chapter 3). Intervening in the prices of a liberalised market is in conflict with EU legislation. Likewise, applying the instruments to bring about and maintain efficiently operating markets is at odds with the (possible) application of instruments to ensure macro cost control. Thus price interventions that are based exclusively on macro budgetary considerations may distort competition in liberalised markets. After all, it is highly likely that market parties will avoid investing in improved quality and efficiency if they have insufficient regulatory certainty that they will earn a return on their investment. Of course there is nothing wrong with intervening in pricing when markets are not working properly. But it is essential that market parties should have had a real opportunity to demonstrate whether the market can in fact operate properly. Markets will not be able to function well if there is insufficient certainty that the pricing freedom introduced will not be overturned by the government for short-term budgetary reasons. The use of Wmg instruments to limit macro costs may therefore impede the development of effective competition and may therefore be inconsistent with other Wmg instruments that are designed to promote effective competition.

2 The set of instruments for determining the existence of and acting in the event of significant market power (SMP) is encumbered by four obstacles.

- The fact that the Wmg allocates the task of quality evaluation exclusively to the Dutch Healthcare Inspectorate (IGZ) may impede consistent evaluation of the effects of SMP both in terms of price and quality.
- The SMP instruments contain an inherent imbalance because the NZa is authorised to intervene if SMP is expected to lead to higher prices, but not – or only indirectly by imposing transparency obligations – if SMP results in poorer quality.
- Determining the existence of SMP ought to be based on a clearly defined market founded on the principles of general competition law. A problem in this respect is that general competition law still lacks an adequate and legally accepted method to define markets in the health care sector. This greatly impedes the process of determining the existence of SMP.
- There is a lack of information about the role and effectiveness of the informal use of the SMP instruments.

3 The current scope of the Wmg is insufficient to prevent misuse of significant market power in the allocation of training places for medical specialists. Therefore, the current Wmg cannot contribute to achieving the Health Ministry's goal of creating these training places by means of quality competition.

Possible Solutions

To tackle the above obstacles, the following possibilities could be considered:

With regard to the conflict between enforcing a macrobudget and creating room for competition:

The most obvious solution would be to abstain from price interventions in health care markets in which room for price competition has been created. However, as a result, if health care costs in the liberalised segment should rise faster than had been projected by the government (for example, if more higher quality care is delivered), the rising costs could be passed on to the regulated segment in order to keep spending within the health care budget (BKZ). To prevent this passing on of costs, the liberalised part could be placed outside the BKZ. To foster effective competition in market segments where room for price competition has been introduced, abstinence of price interventions could be guaranteed, provided that effective competition has evolved within a specific, pre-defined period (e.g. three years) (See also the proposed solutions under 2 below).

With regard to the effectiveness of the SMP instruments:

The NZa could be given the authority 1) to independently assess the effects of the SMP on the price/quality ratio on the basis of recommendations from the Dutch Health Inspectorate (IGZ), and 2) to impose conditions in case of SMP in order to reduce the risk of quality impairment.

Since the requirements of general competition law can greatly hamper effective use of the SMP instruments, it is worth considering the development of a different set of assessment criteria for health care, to which the Wmg would be amended accordingly. Such health care-specific assessment criteria will be relevant if it should transpire that in practice the effectiveness of the SMP instruments is limited. Furthermore, compliance parameters of this nature must be compatible with EU legislation (e.g. art. 3 of Regulation 1/2003).

In order to reduce legal uncertainty about the method of market definition to be adopted, the NZa ought – in collaboration with the Netherlands Competition Authority (NMa) – to set up and publish guidelines as soon as possible on the exact way that health care markets are to be defined geographically. These guidelines ought in any case to provide clarity about the successive steps to be taken and the method of market definition adopted. Taking account of the specific characteristics of health care markets, the guidelines should reflect as closely as possible the case law of general competition legislation (unless health care-specific assessment criteria are opted for – see above). In order to be better able to assess the effectiveness of the SMP instruments, it is recommended that an analysis should be conducted of the effectiveness of informal policy with regard to market parties with a presumed SMP position. This kind of analysis could consist of recording the actions that have been undertaken by the NZa and the behavioural responses which have resulted from these actions. (See also Chapter 5: Supervision)

With regard to the scope of the Wmg:

> In order to be able to intervene where there is significant market power in the allocation of training places for medical specialists, a solution may be to incorporate relevant medical studies within the scope of the Wmg.

2 The set of instruments for cost control: regulation of prices and performance

The Wmg contains various instruments for implementing cost control. These instruments are applicable both to market segments in which regulation is paramount, and in more liberalised segments of the health care sector, where pricing freedom has been introduced, together with the ensuing autonomy for health care providers and health insurers. Price regulation takes place through the NZa, on the basis of policy rules it has established and where required by a directive from the Minister of Health, Welfare and Sport.

Possible obstacles

On the basis of case-law of the European Court of Justice, it may be argued that the Court is likely to declare pricing directives for the A-segment (care that is financed in fixed budgets), and for fees in the B-segment (liberalized segment, including regularly occurring hospital treatments of a non-urgent nature) to be in conflict with the EU principle of freedom of movement and of services. At the same time there are sound arguments in favour of a possible justification of this conflict with regard to the current pricing structure. In this respect it is of great importance that a close examination should take place of whether specific activities that are still included in the regulated A-segment should not be transferred to the freely negotiable B-segment. If there should later be a return to regulation, for example by restoring activities from the B-segment back to the A-segment, this would require ample justification, with proof of compliance with the four conditions that would justify interference with the fundamental freedoms guaranteed by the Treaty. These conditions are that a return to regulation must be applied in a non-discriminatory manner; it must be justified by overriding reasons based on the general interest; it must be suitable for securing the attainment of the objective which it pursues; and it must not go beyond what is necessary in order to attain that objective[3].

A problem with the assessment of cost development in the B-segment in hospitals is that there is still uncertainty surrounding the development of real costs. While positive developments are being identified, there is no clear insight into the actual situation. It is therefore particularly difficult to reach a well-informed decision on this point as to whether intervention in cost development is required or whether room should be given to the markets as they develop. On the one hand, the positive signals might well give reason for a hands-off policy, with the parties involved receiving room to further develop this liberalised segment of the health care market. On the other hand, the

[3] See ECJ Gebhard [1995] Case C-55/94 ECR I-4165, paragraph 37, Haim [2000] Case C-424/97 ECR I-5123, paragraph 57, and Mac Quen and others [2001] Case C-108/96, ECR I-837, paragraph 26.

government has a certain responsibility to manage total costs, and on this basis might well opt for a form of cost control, although only if it should transpire after a number of years that effective competition was underdeveloped in that market segment, resulting in excessive growth of the health care costs concerned.

As is the case with hospitals, an experiment with pricing freedom commenced in the field of physiotherapy in early 2005. After monitoring by the NZa, the health minister extended the original experimental period of two years by a further year. Here too, problems emerged initially. After rising strongly at an early stage, the contract prices stabilised, which safeguarded affordability, according to the NZa. As a result, on 1 January 2008, free market pricing was officially introduced for physiotherapy. The most recent data from Statistics Netherlands (CBS) show that in recent years there has been an increase in the number of people attending a physiotherapist. The reason for this rise is not clear. Remarkably, the NZa has not conducted an analysis of these developments. Given such a unique situation, the first instance of pricing freedom in a market, with the relatively favourable condition of an oversupply of health professionals, it might be expected that developments would be closely monitored, in order to ascertain how costs and volume were panning out and whether the market was indeed becoming more efficient and whether the public interest was being served by improved accessibility, quality and affordability. The absence of this kind of analysis means it is not really possible to establish whether developments regarding physiotherapy are going in the right direction, and an opportunity is being lost to learn from this situation.

Possible solutions

It is important that the NZa should continue intensive monitoring of both price and volume development in all the market segments that have so far been liberalised. While this is currently the case where hospital care is concerned (B-segment), it is not true for physiotherapy. Only intensive monitoring will reveal the extent to which markets are operating efficiently, and will shed light on how much these markets are serving the public interest. Only then can lessons be drawn from these developments and applied to other markets yet to be liberalised.

Sound monitoring is furthermore important because a return from pricing freedom to price regulation will not be easy to achieve within the context of EU legislation, and would require well-founded reasons for doing so.

Finally, there is a case for allocating greater accountability for monitoring cost development to health insurers and health care agencies. It is the insurers and the agencies that negotiate prices and volumes. These organizations should therefore be afforded greater interest in monitoring total cost development. This mechanism could be more effective in a specific sense than the more generic measures that governments have at their disposal.

3 Instruments for publicising information on the available options

A new element in the Wmg is mandatory publication of information on the options available to clients by health insurers and health care agencies. This is laid down in sections 38 and 40 of the Act. The legislation also assigns to the NZa the responsibility of supervising compliance with this obligation. The government has adopted policy measures to support the development of information on available options. The disclosure and usage of this information is developing slowly. Research is being conducted on which kind of information should be offered and the market parties are investing considerably in developing the information required. An important role is played by the Dutch Health Inspectorate (IGZ) in this respect. The NZa supervises the realisation of information on options via monitoring activities, and sees to it that the market is not remiss in disclosing the information.

Greater availability of information on choices has resulted in more selective, consumer-like behaviour among clients in the health insurance market. Thus insurees have a somewhat stronger position. However, this pattern is not yet apparent in the health care supply market, where patients cannot be said to behave as selective consumers. The question therefore arises as to whether the position of the consumer has actually become stronger as a result of the publicising of information on the available choices. There are indications from various angles that increased transparency among health care providers has boosted the quality of care. However, it is entirely possible that there may be other, more defensive effects.

Possible obstacles

Information is available in the health insurance market about premiums, the quality of service offered by the health insurer and to a certain extent about health care purchasing. It is often difficult for consumers to ascertain the quality of the care purchased by the insurer. While consumers use information for making choices, these choices are chiefly based on the premium price, because this information is readily available and easy to compare, while the gap in service quality between insurers has all but closed, and the information about health care purchasing is too limited. Furthermore consumers restrict their choice of insurer greatly by choosing from a limited number of available group insurance schemes. The vast majority of these group schemes tend to negotiate a deal on the basis of premium payable and not on the basis of the quality of the contracted care. Because both consumers and insurers base their choices chiefly on the premium price, as do most group schemes, the choices made in the health insurance market do not yet influence the quality of the care purchased by health insurers.

Despite the fact that considerable effort has been made in recent years in the area of fostering the availability of public information on quality in the health care market, there is still insufficient information on quality available to consumers. Equally, consumers have virtually no insight into pricing. Consequently, they have little understanding of the price-quality ratio of the health care offered. It may therefore be asserted that the health care market is not yet subject to the scrutiny of well-informed consumers who are in a position to make informed choices on the basis of knowledge about quality and prices.

A system in which consumers make informed choices and can thus influence the quality of care appears, contrary to expectations, not yet to be reality. In the health insurance market, consumer choices are still largely based on the premium price. With regard to the health care supply market, little is known as yet about the usage of information on options and the way in which consumers make choices. Nonetheless, there are indications from various quarters that an improvement in quality has taken place in recent years in the health care market, and that this is largely due to the growth of transparency[4]. Increased transparency means that health care providers do not so much fear losing clients as the risk of reputational damage if they fail to publish their results and if their results turn out to be poor. This is a different mechanism than that originally envisaged. And whether it creates a problem is unclear. It is clear, however, that the way in which transparency works is different from how it was originally intended.

Possible solutions

Fostering a sound system of information on options takes time and patience, and is therefore a process which requires government support, possibly by means of a lasting policy measure. In order to create greater insight into the mechanism of transparency development, choice-making behaviour and quality improvement, the government might well consider the possibility of sound research in this area. In this respect, attention could be paid to the consequences of the assertion that while transparency-creating information does influence the behaviour of insurers, this is mainly on account of concern for their reputation.

In order to ascertain the price-quality ratio of a direct cover insurance policy, it is necessary to have information in a timely manner about the health care to be purchased and to be able to make comparisons. Otherwise, consumers will base their decisions only on the price of the premium. Health insurers will therefore have to ensure that timely information is available about their health care purchasing, before clients choose a new policy; and insurers must also consider how the information about the quality of the care contracted can best be presented.

Because it is difficult for consumers to make informed decisions this means that their current choice-making behaviour exerts little influence on health care providers. The combined effect of pressure from individual patients at micro level and from patient organisations and consumer organisations at meso and macro level may substantially strengthen the position of consumers and patients. For patient and consumer organisations to be better able to develop this role, they will require support.

4 Supervision

In order to prevent political bodies from interfering directly with the market parties in the health care market, it was decided to have supervisory activities carried out by a new, sector-specific supervisory body, the NZa. The activities and statutory basis for the NZa are laid down in the Wmg.

[4] See also: The Netherlands Organization for Health Research and Development (ZonMw) 2009.

According to the Wmg, the supervisory body should operate with restraint where possible, but intervene effectively and decisively where necessary. The explanatory memorandum to the Act describes three main tasks of the NZa[5]. These are market supervision, supervision of the proper execution of the Health Insurance Act (Zvw) and supervision of the proper and effective execution of the Exceptional Medical Expenses Act (AWBZ). By performing these tasks, the NZa oversees the health insurance market, the health care purchasing market and the health care provision market as well as health care providers and health insurers in both curative care and long-term care.

Possible obstacles

The Wmg envisages that the supervisory authority will be 1) independent and adopt a hands-off approach and 2) effective and decisive[6]. While the NZa fulfils the first of these roles, little is to be seen of the second. This is due to two main factors. First, the fact that health care in the Netherlands is in a period of transition, and second, the supervisory style adopted by the NZa itself.

Transition

Three years after the introduction of the Zvw, the Wmg, the Social Support Act (Wmo) and changes to the Exceptional Medical Expenses Act (AWBZ), the implementation of the complex new health care system is still ongoing. During the interviews[7], the representatives of the supervisory bodies indicated that the right footing with other supervisory bodies is still being sought and that this is a learning process. The same is true for the relationship with political bodies. Likewise, the political bodies – both parliament and minister – appear to be in the process of growing into their new role. Because various entities are still evolving, there is as yet a rather obscure picture of task definition for the various actors and of the precise role of the NZa, and this is also unclear in the Wmg. So while the NZa was set up for the purpose of supervising the transition, paradoxically it is itself still in the process of finding its own path. Under these circumstances, effective, decisive supervision can hardly be expected until the various footings have been established.

The modernisation of the AWBZ is also part of the system change, and this transition is still ongoing. The explanatory memorandum states that the cabinet is deliberating on the future of the AWBZ and the position of health care agencies within the implementation of the AWBZ, and that until this is decided, little will change in the required supervision[8]. Thus the cabinet is simply marking time, whereas it might have been better to have strengthened the supervisory structure and the accompanying set of instruments. While the formal instruments can be used to direct compliance, if breaches continue or re-occur, a financial penalty will not have much effect because these health care agencies do not have their own finances or an owner; they only have

[5] Parliamentary reports II 2004-2005, 30 186, no.3, p.5 (Explanatory Memorandum)
[6] Parliamentary reports II 2004-2005, 30 186, no.3, p.38 (Explanatory Memorandum)
[7] Health Inspectorate (IGZ) interview, (25 February, 2009); NMa Interview (24 March, 2009); Interview with NZa officials (2 March, 2009).
[8] Parliamentary reports II 2004-2005, 30 186, no. 3, p. 28 (Explanatory Memorandum).

a contractor (viz. the insurer), according to an NZa spokesperson[9]. Accordingly, the instruments are not up to the task[10], and this hampers the effectiveness of the supervision. In fact, it is still questionable whether the AWBZ-health insurer can actually be penalised on the basis of the authority mandated to the health care agency.

Supervisory styles

In paragraph 5.2 we have presented three individual perspectives of supervision as put forward by Mark Bovens et al. [11]. These are the democratic, the constitutional and the cybernetic or learning perspectives. We stated that in using these perspectives, a proper balance is required in order to be able to conduct adequate supervision, while it is possible that a particular perspective will be favoured, for instance during a specific period or in relation to a specific topic.

Particularly in relation to the application of the instruments, it may be asserted that the NZa continues to adopt a chiefly cybernetic, learning style of supervision. Formal instruments such as the SMP instrument are seldom put to use, if at all (see also Chapter 3). Instead, the NZa still tends to make more use of less formal instruments such as cautionary interviews, or a 'raised eyebrows approach'. This is partly due to the policy adopted by the NZa in view of the above described transition period, and partly to the (nature of) the instruments and the proposed supervisory policy contained in the Wmg. By virtue of the Wmg, the NZa has the authority to act in a more repressive way, but so far it has opted not to do so. However, the choices it has made are in line with that part of the Wmg policy theory that states that the NZa should foster confidence among market parties and create room for them to function; at the same time the NZa actions are less in line with the repressive role which is equally part of the Wmg's policy theory. Thus the Wmg aims at simultaneous use of both the cybernetic and the constitutional approach. In our analysis, the NZa is in the process of seeking an acceptable balance between these two perspectives.

The approach adopted by the NZa appears to have been influenced by the combining together of regulatory and supervisory tasks. These two functions demand entirely different dynamics and styles, including and especially regarding the relationship between the supervisory body and the entities under supervision; and if an organisation has to make use of both styles, it will be difficult, particularly for a newly appointed supervisor, to adopt a repressive approach while maintaining a relationship with the market parties. According to an NZa spokesperson with regard to the combining together of roles, regulatory and supervisory tasks should be allocated to separate functions, but both should learn from one another[12]. In view of the above described supervisory-role teething problems and the transition affecting many parts of the health care sector, this attitude would appear to be reasonable. At the same time, it may be asked whether we might see more of the NZa's watchdog role at a later stage.

[9] Interview with NZa officials (16 April, 2009).
[10] Interview with NZa officials (16 April, 2009.
[11] Bovens, 2005; Bovens et al., 2008.
[12] Interview with NZa officials (16 April, 2009).

However, the nature of the set of instruments that the NZa has at its disposal makes it doubtful whether this will indeed be the case in the near future. There are two reasons for this. First, the instruments are chiefly preventative in nature; the explanatory memorandum emphasises that the NZa's enforcement instruments have various purposes. Thus the order directing compliance and the order under threat of a fine are more preventative in nature (designed to prevent breaches), whereas the financial penalty order has a more repressive character, according to the Explanatory Memorandum[13]. Because the NZa opted during the early days for a limited use of its formal enforcement instruments, and when used at all, the order directing compliance was used first, the emphasis leans heavily towards informal and preventative supervision. There still appears to be insufficient accountability for the use of the informal instruments, such as 'raised eyebrow' interviews, and this blurs the status of the instrument package.

Furthermore, as has already been discussed in Chapter 3, the formal, repressive instruments at the disposal of the NZa are cumbersome, to say the least. According to NZa spokespersons, the formal instruments are fraught with legal difficulties, and the procedures for a fine to be imposed can take months[14]. Clearly, meticulousness is required, but slow legal procedures do not contribute to the effectiveness of the supervision. The duration of legal procedures and the accompanying disproportionate number of working hours required are therefore a problem for the NZa[15]. Accordingly, the application of these instruments in a more repressive style, which would balance out the learning perspective, requires substantial investment.

The successful implementation of more repressive elements of enforcement is hampered by both the direct involvement of the NZa in the health care market and the role and position occupied by the NZa in relation to other involved (market) parties. It is therefore questionable whether the NZa can successfully make the transition to more repressive supervision.

Possible solutions

Based on this evaluation of supervision as regulated by the Wmg, three possible solutions are proposed.

In order to clarify task delineation and role definition for both the NZa and the Minister, the as yet open standards of compliance testing could be assigned to the Minister. At the same time, there will always be cases when it will be necessary to define open standards for the purpose of executing supervisory tasks. Transparency is required in this respect.

A second possibility would be to formulate a clear task delineation between the NZa and other supervisors, in order to define the specific role of the NZa and strengthen its position. Since many of those involved undergo a developmental process, it would be wise not to close the door completely between the various tasks and parties involved. Regular discussion and, if necessary, adjustments are important.

[13] Parliamentary reports II 2004-2005, 30 186, no. 3, p. 27 (Explanatory Memorandum).
[14] Interview with NZa officials (16 April, 2009).
[15] Interview with NZa officials (2 March, 2009).

Finally, the NZa ought to consider seeking a better balance in its supervisory style, which currently exhibits many characteristics of a learning style. Its vision statement already anticipates a shift from more preventative to more repressive policy. It would appear logical to put this into practice. From this point of view, a critical look should be taken at the enforcement instruments (including the SMP instrument) that the NZa has at its disposal.