



To the Minister of Health, Welfare and Sport

Subject : Advisory letter on *policy regarding the Exceptional Medical Procedures Act*
Your reference : -
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Dear Minister,

Your letter of 13 June 2007 to the President of the Dutch House of Representatives and your recent exchange of letters with the Dutch Federation of University Medical Centres (NFU) concerning the Special Medical Procedures Act give me cause for a number of reflections on this legislative instrument's position and importance from the point of view of the role and task of the Health Council of the Netherlands. I would also like to take the opportunity to set out how the Council can assist now and in the future with the operation of the Special Medical Procedures Act, in the changing landscape of health care. I have presented and further explained these ideas in the accompanying memorandum.

The Health Council has long been involved in advising on policy concerning special, tertiary care provisions, first within the scope of section 18 of the Hospital Provision Act and subsequently in relation to the Special Medical Procedures Act. This is mainly approached from the point of view of the relationship to current scientific knowledge: what scientific information is available on the efficacy, cost-effectiveness and safety of a special medical procedure? And, in the light of this: how can that procedure be applied in the Netherlands under conditions that guarantee optimum safety and quality, cost-effectiveness and access? This means that the Health Council's recommendations correspond closely with your policy of using the licensing system of the Special Medical Procedures Act to regulate the introduction and distribution of special medical procedures in a way that contributes to optimum quality and cost-effectiveness in health care.

In recent decades the adopted policy on special medical provisions in the Netherlands and its substantiation, also by the Health Council, can be deemed to have been a success. There is high regard in other countries for the way in which the Netherlands guarantees the quality and



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availability of tertiary health care. The concentration policy adopted in connection with this is also based on knowledge obtained from scientific research and clinical experience, namely that there is a clear connection between a procedure's volume and its results. Other appreciated aspects of the policy are that the cost-effectiveness of special procedures in the Netherlands has been systematically evaluated in recent decades and that their concentration facilitates their evaluation.

You indicate clearly in your letter that you also intend to retain the Special Medical Procedures Act as an instrument within the context of the new policy but in an updated, more dynamic form. I subscribe to your approach that the quality and safety of the health care provided should primarily be anchored in professional guidelines for medical practitioners and in the supervision of quality, as implemented by care institutions and the Health Care Inspectorate and defined in the Care Institutions (Quality) Act. Regulation by government with the aid of the Special Medical Procedures Act should be preserved for rare and complex procedures, which are covered by special infrastructural preconditions and for which it is advisable to schedule access at the supraregional level. Situations may also be involved whereby market forces fail to produce the required volume of procedures in a hospital (catchment areas too small, competition too strong) and health care may consequently not be cost-effective. If circumstances of this kind can be expected, it might be advisable to assess quality-determining factors beforehand, on the basis of a licence.

I share your opinion that application of the Special Medical Procedures Act does not mean that this regime will continue to apply for every procedure. This means that the entry and exit criteria should be clear and applied consistently. By providing its advice, the Health Council will continue to contribute on the basis of these new starting points to ensure that the quality and cost-effectiveness of tertiary health care in the Netherlands remains at a high level.

Yours sincerely,

(signed)
Professor J.A. Knottnerus
President

Special Medical Procedures Act Appendix

The future application of the Special Medical Procedures Act and the Health Council's role

Foreword

On 13 June 2007, the Minister of Health, Welfare and Sport sent the President of the Dutch House of Representatives a letter concerning the position and operation of the Special Medical Procedures Act.¹ In the aforementioned letter, he discusses the way in which the Special Medical Procedures Act is deployed as a control instrument, and he unfolds various proposals for modernising the Special Medical Procedures Act as an instrument of regulation, to achieve better gearing with recent changes in the health care system. The starting point is maintenance of the existing system of the Special Medical Procedures Act, but also greater emphasis on making the available set of instruments more dynamic, as well as restraint in its application.

The aim of this memorandum is to analyse how these proposals can be put into effect in practice in the updated health care system, and the contribution to this that the Health Council can make in its advisory role is also discussed.

Brief history of the Special Medical Procedures Act

The Special Medical Procedures Act entered into force on 14 November 1997 and superseded section 18 of the Hospital Provision Act. The aim of the Special Medical Procedures Act is to regulate special medical procedures and provisions, which are also referred to as 'tertiary health care'. This concerns health care at a limited number of locations, also known as supraregional or national provisions.² Tertiary preferred health care may also be partially seen as tertiary health care; this is the specialist health care for patients with special disorders for which a precondition is the combination of multidisciplinary expertise in an institution which serves as the final referral address; see for example the current discussion on the treatment of oesophageal carcinoma, and that on the practice of aortal surgery.

The key feature of regulation based on the Special Medical Procedures Act is the controlled introduction and practice of special medical procedures by means of a licensing system that supervises the number and distribution of locations. The concentration and distribution policy adopted in this way helps optimise the safety and quality and the cost-effectiveness of health care.³

Present scope of the Special Medical Procedures Act

The following special medical procedures and provisions are currently regulated under the Special Medical Procedures Act:

a) With the aid of section 2 of the Special Medical Procedures Act (regulation on the basis of a licence requirement)

- All types of stem cell/bone marrow transplants (autologous, allogeneic), in children and adults
- Neonatal intensive care and special perinatal health care
- Special interventions for the heart (cardiopulmonary surgery and intervention cardiology), in children and adults
- Clinical genetic research and genetic counselling
- In-vitro fertilisation
- Specialized neurosurgery
- Radiotherapy
- Organ transplants (all organs, including islets of Langerhans but excluding other tissue/cell material), in children and adults

b) With the aid of section 3 of the Special Medical Procedures Act (regulation on the basis of a general prohibition)

- Gender selection for non-medical reasons
- Clinical application of xenotransplants

¹ Letter to the President of the Dutch House of Representatives, reference CZ/TSZ-2749699, dated 13 June 2007.

² See Special Medical Procedures Act: "Wet op bijzondere medische voorzieningen", Schuurmans & Jordens edition, 2001, page 24.

³ See the Explanatory Memorandum to the Special Medical Procedures Act concerning 'vital interests'. MvT II, 24 788, no. 3, page 9-10.

c) With the aid of section 8 of the Special Medical Procedures Act (regulation by provision of funding)

- Knowledge centres for employment-relevant disorders
- Specialized trauma care
- Centres for treating haemophilia
- HIV treatment centres
- National knowledge centres in the Mental Health Service (including psychiatry for children and adolescents, geriatric psychiatry and eating disorders)
- Organ removal teams for organ donations

Evaluation of the Exceptional Medical Procedures Act

In accordance with the provisions of section 20 of the Special Medical Procedures Act, the Act was evaluated for the first time in 2001, whereby the efficacy and the effects of this set of legislative instruments was assessed.⁴ Conducted under the aegis of the Netherlands Organisation for Health Research and Development (ZonMw), the evaluation's summarising conclusion was that 'each of the instruments provided by the Special Medical Procedures Act has proven its efficacy and that collectively they are necessary and sufficient for achieving the required control and regulation of special medical procedures'. The researchers provided comments, some critical, on the following components:

- Application of the licence requirement (section 2) has not limited access to special health care; concentration prevents inadvisable distribution and promotes quality; licensing only a single, national centre makes health care vulnerable.
- Application of the financial incentives (section 8) promotes access to health care.
- Criteria for the application of the Special Medical Procedures Act are generally too broad in scope and vague; this applies to the licence requirement, the general prohibition and the regulations on entitlement).
- Application of section 2 (licence requirement, concentration policy) contributes in a general sense to promoting quality and controlling costs. However, this instrument is not applied consistently.
- Application of section 8 could be expanded; this would increase quality but would generate extra costs (yet might save costs in the long term).
- There are shortcomings in monitoring of the observance of the provisions of the Special Medical Procedures Act and the supervision of quality.
- There appear to be no problems with the Special Medical Procedures Act's relationship to European legislation and regulations but further study is recommended.

Responding to this evaluation, the former Minister of Health, Welfare and Sport (in 2002)⁵ concluded that 'the scheduling of tertiary health care will continue to be a task of government'. A key point in this is the assurance of quality, cost-effectiveness and appropriate use on the basis of medical, ethical and social aspects. To this end, government should have an instrument that can encourage, concentrate, inhibit or prohibit developments associated with special medical procedures. The evaluation showed that in general the Special Medical Procedures Act provides such a possibility. The minister therefore concluded that the application of the Special Medical Procedures Act can continue but that some points needed to be improved. The proposals for the application and amendment of the Special Medical Procedures Act that the minister has since put before the Dutch House of Representatives can be seen as a response to the evaluation.

Current intentions of the Ministry of Health, Welfare and Sport

In his recent letter (13 June 2007) to the Dutch House of Representatives, the present Minister of Health, Welfare and Sport maintained the conclusion that the system of the Special Medical Procedures Act will continue, and he also indicated the changes and improvements he seeks to achieve.⁶ The changes are closely related to current changes in the health care system (control of demand, increase in the operation of market forces, emphasis on self-regulation). These proposals are summarised below:

- Limited application of the Special Medical Procedures Act. The starting point for the introduction and distribution of new health care is self-regulation; the Special Medical Procedures Act only plays a role as an instrument for regulation if there is a likelihood of an undesirable situation arising without government intervention (such as danger arising in the case of health care that has not yet been fully developed or less than optimal quality on account of ineffective quality assurance).

⁴ Report on the Evaluation of the Special Medical Procedures Act. ZonMw, November 2001.

⁵ Letter to the President of the Dutch House of Representatives, reference IBE/2296703, dated 12 July 2002.

⁶ Letter to the President of the Dutch House of Representatives, reference CZ/TSZ-2749699, dated 13 June 2007.

- Tightening of the objectives of the Special Medical Procedures Act. Regulation through the Special Medical Procedures Act primarily focuses on proper distribution, concentration and access, and not in the first place on monitoring the quality of health care. This is generally the concern of the Care Institutions (Quality) Act.
- Need to make the Special Medical Procedures Act more dynamic. Besides tightening the entry criteria and making them more specific, the limits also need to be placed on application of the Special Medical Procedures Act over time. Scheduling decisions and licences will be subject to a maximum period (four years or a shorter period, if appropriate).
- A carefully managed exit policy. Promotion of the outflow of provisions from the Special Medical Procedures Act requires clear criteria, the establishment of an effective quality system, reinforcement of the individual responsibility of medical practitioners.
- Restraint in the use of financial incentives based on section 8 of the Special Medical Procedures Act. It would be more advisable for any financial support that may be required to go through the general DBC (diagnosis treatment combination) system, rather than through special budget parameters. Knowledge/expertise centres should preferably be promoted by means of facilities such as project subsidies.

Comments on the objective of the Special Medical Procedures Act

The Minister of Health, Welfare and Sport indicated in his letter that the primary aim of the Special Medical Procedures Act is the regulation of the use of special medical procedures, by enabling him to prohibit, limit or encourage their use and access to them. The licensing policy is intended to create proper distribution of health care provisions and access to them, and to optimise their cost-effectiveness. Concentrating special provisions at a limited number of locations is an important way of achieving this. The minister also indicated that the Special Medical Procedures Act is not of itself intended as a means of pursuing a quality policy (quality assurance and quality control), as this is mainly subject to the Care Institutions (Quality) Act. Specific quality criteria for a special procedure must therefore come from the Care Institutions (Quality) Act.

The above distinction is clear but also somewhat artificial. The underlying objective of the licence requirement and the establishment of concentration is actually to promote optimum safety, quality in health care, as well as optimum cost-effectiveness.⁷ This can be achieved by bringing together expertise in a multidisciplinary setting, with a situation-specific infrastructure, in which scale effects play a role. After all, it has often been demonstrated that there is a strong link between volume (the extent to which the procedure is carried out) and quality (results, complications, mortality), and that a large volume can also lead to cost benefits. A study recently confirmed this for a special procedure such as perinatal/neonatal intensive care.⁸ The arguments favouring a concentration policy are therefore rightly also determined by the attention paid to quality. A scheduling decision and the individual licences based on it will therefore at least be able to refer to relevant quality criteria and standards, such as those laid down in professional guidelines or the Health Council's advisory reports. However, the adoption of a **general quality policy** (development of a quality system, formulation of performance indicators, and registration of treatment results) and the **supervision of quality** (role of the Dutch Health Care Inspectorate and quality inspections by the profession) remain pre-eminently the field of the Care Institutions (Quality) Act. Consequently, a regular quality policy based on the Care Institutions (Quality) Act will be appropriate for some of the special procedures, especially those which have become a stable part of health care provided in the Netherlands, in terms of their clinical development, cost-effectiveness and distribution. However, the most effective method for some of the other special procedures, especially those which are rarely used, complex and still largely being developed, appears to be a combination of promoting quality beforehand (by placing or keeping a new special procedure/provision under the Special Medical Procedures Act, and issuing or enforcing a licence) and supervising quality afterwards (supervision by means of the Care Institutions (Quality) Act). In the case of special provisions, experience in the field has also shown that the licence requirement in combination with a policy that focuses on concentration is an effective way of preventing fragmentation of health care between too many hospitals (whereby the volume of procedures falls below the required quality standard). Supervising the quality of certain special procedures only after they have been performed cannot provide adequate assurance that fragmentation of this kind will be prevented, and may therefore result in reduced safety and quality, as well as loss of capital. Examples of this include congenital surgery and heart transplants in young children. Another aspect is that in special procedures in acute cases (such as IC neonatology, special trauma care, and acute cardiological interventions), the emphasis is not only on

⁷ See the Explanatory Memorandum to the Special Medical Procedures Act concerning the 'vital interests' criterion. MvT II, 24 788, no.3, page 9-10.

⁸ NEJM. CS Phibbs et al. Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants. 2007; 356: 2165-75.

optimum quality but also on 24-hour availability and accessibility. This requirement should be stipulated upon establishing such a procedure; after all, solely controlling demand on the basis of incentives from the market would not provide sufficient encouragement to achieve the required quality and continuity.

Finally, it is pointed out that safeguarding quality and cost-effectiveness by means of a concentration policy (promoting quality beforehand) may also be relevant for procedures that have not been placed under the Special Medical Procedures Act or that have already ceased to be governed by it (such as oesophageal operations or aortal surgery); this requires regional agreements between centres on referrals.

Comments on the entry policy

The aforementioned evaluation of the Special Medical Procedures Act indicated that this instrument is not used consistently, also because the criteria are vague. What makes a medical procedure ‘special’ for the purposes of the Special Medical Procedures Act is also not described in the Act or a decision. The general criterion for application of section 2 (prohibited unless licensed) is ‘vital interests’. This is aimed at situations whereby a) there is a need for concentration from the point of view of quality, efficient use and costs, or b) not applying regulations could lead to an unacceptable risk (poor quality or social and ethical dilemmas but also a lack of careprovision).⁹ Therefore, the Minister of Health, Welfare and Sport actually determines when those situations play a role and, consequently, which procedures are ‘special’. The set of related considerations now referred to in the Minister of Health, Welfare and Sport’s letter, which form the basis for determining whether regulation pursuant to the Special Medical Procedures Act should apply, provides a proper and clear framework for putting the ‘vital interests’ criterion into effect, and provides specific criteria for decisions on the inclusion of health care provisions under the Special Medical Procedures Act. These criteria also correspond well with the criteria based on scientific considerations (evidence-based medicine), such as efficacy, safety and cost-effectiveness, which are usually adopted in the Health Council’s advisory reports.

Suggestions on the exit policy

Pursuant to the current section 2, subsection 2, of the Special Medical Procedures Act, a ministerial regulation by virtue of which a special procedure has become subject to a licence requirement ceases to apply no later than four years after entering into force. Scheduling decisions and licences issued pursuant to the Special Medical Procedures Act are currently, by definition, already temporary. The reconsideration of the entry decision or review of the scheduling decision will therefore have to take place long before a regulation’s expiry. The legislator may therefore allow the procedure concerned to exit after four years but also has the option of continuing the prohibition by order in council. Therefore, a definitive exit after four years is not automatic but the continuation of a licence requirement may be considered, in which case the aforementioned assessment framework applies once again. This system has thus far usually resulted in the continuation of the licence requirement for procedures subject to the Special Medical Procedures Act but provisions such as CT and MRI diagnostics, nuclear medicine and, more recently, haemodialysis, have actually exited. The Minister of Health, Welfare and Sport’s proposal to draft temporary decisions and licences with a shorter term than four years from now on, if accountable, is in line with the intention of the Special Medical Procedures Act and the wording of the Act.¹⁰

The minister states that the assessment framework will be useful in the opposite sense, if the question arises of whether a procedure covered by the Special Medical Procedures Act will be permitted to exit (after four years or a shorter or longer period determined by the minister). This framework and the set of questions it includes are clear in themselves but need to be worked out in greater detail for that purpose and put into operation. For example, the task of developing a quality system cannot simply be assigned to individual licence holders but will have to be assigned to the professional group as a whole. The Health Council can play a support role in this. Likewise, the assessment of when a quality system has been sufficiently developed to allow the procedure concerned to exit the scope of the Special Medical Procedures Act without risk will have to be made more specific: who will make the assessment and on the basis of which criteria? Moreover, the assessment of whether a crystallised indication for the procedure exists will also depend on an analysis of the latest scientific developments.

⁹ The Explanatory Memorandum to the Special Medical Procedures Act (MvT II, 24 788, no. 3, page 9-10) refers to ‘vital interests’, if ‘in the absence of the protection provided by the Special Medical Procedures Act, and also bearing in mind any social and ethical aspects associated with the procedure, an unacceptable risk would arise of the procedure being performed without adequate quality assurances being in place’.

¹⁰ See section 2, subsection 2, of the Exceptional Medical Procedures Act.

Generally speaking, the procedure's exit from the scope of the Special Medical Procedures Act should be based on a careful, transparent and consistent procedure, whereby the possible consequences of the procedure's exit must be the main concern, rather than simply the stipulated period. It seems reasonable to assume that once government has decided to regulate a procedure, the responsibility for the procedure's quality and access to it will only be transferred to the field, in this case the professional group, following careful consideration of the pros and cons of such a proposal. From the standpoint of careful decision-making too, a procedure's exit from the scope of the Special Medical Procedures Act cannot simply occur automatically. A reasonable transitional period will have to be taken into account. Finally, it may emerge from the application of the assessment framework proposed by the minister and the criteria that certain special procedures do not qualify for exit. This could possibly apply to procedures in which control of demand through the market affects the required optimum quality level and volume, as in situations in which the patient has no other options (for example a heart transplant for a child and neonatal IC). The same may apply to provisions or procedures involving important ethical and social issues, such as those concerning the beginning and end of life.

The Health Council's role in the amended policy on the Special Medical Procedures Act

The Health Council has long had an advisory role in the regulation of special health care provisions (originally on the grounds of section 18 of the Hospital Provision Act, and subsequently pursuant to the Special Medical Procedures Act), in connection with the question of whether 'vital interests' give cause to introduce or continue a licence requirement (pursuant to section 2 of the Special Medical Procedures Act) and the question of whether an experimental treatment should be subject to a prohibition (pursuant to section 3 of the Special Medical Procedures Act). The Health Council mainly approaches these questions on the basis of the latest scientific developments, whereby the determining factors are scientific evidence and concerns about safety and quality and the cost-effectiveness of health care. The Council's method of working ensures caution (committees with a multidisciplinary composition), scientific quality (review by standing committees), and independent advice (disclosure procedure and transparency about the interests of experts).

The Health Council is of the opinion that its advisory task provides it with the basis for making a substantial contribution to working out and putting into effect the minister's proposals for modernising the Special Medical Procedures Act.

In the first place, a role for the Health Council would appear to be that of identifying medical procedures that qualify anyway for designation as a 'special procedure' (on the basis of monitoring and identifying issues on the scientific horizon, as well as an ethical analysis). In the case of an entirely new type of health care procedure, it is relevant to ask whether any scientific evidence already exists and whether a fully developed indication for the procedure is available. It may also be necessary to analyse whether a clinically relevant relationship exists between the procedure's volume and its outcome, which should have consequences for the extent to which the health care is concentrated. This assessment may give cause to recommend a licence requirement (section 2) or even a general prohibition (section 3), or to note that self-regulation or certification would suffice. The set of related questions and criteria that has been defined can be used as the basis for developing a more coherent view of the regulation of tertiary health care and tertiary preferred care, and the Health Council will be able to provide a more focused indication of the scientific considerations that should form the basis of any type of control that may be advisable.

In the second place, the Health Council can continue to advise on the drafting of new scheduling arrangements (requirement estimate on epidemiological grounds, well-considered geographical distribution or concentration, the required quality level) for procedures placed under the Special Medical Procedures Act. Especially now that the minister wishes to shorten the term of these decisions, it will be necessary when drafting a decision to take into account a responsible period and conditions for exit, including the development of a proper quality system by the professional group. The Health Council can make allowances for this in its advice on the latest scientific developments.

In the third place, during the period before the expiry of the term stipulated pursuant to the Special Medical Procedures Act, the Health Council can advise on the relevant exit criteria (such as the existence of a proper quality system, the availability of evidence-based professional guidelines, performance indicators and results registration). Substantiation based on scientifically tested findings concerning safety, quality and cost-effectiveness will be provided, in the event of the Council concluding that the procedure's exit from the scope of the Special Medical Procedures Act would lead to unacceptable situations.

An additional point for consideration is that the Special Medical Procedures Act no longer includes a government obligation to obtain advice about entry and exit decisions concerning section 2 regulations. The Health Council is not explicitly named in the Special Medical Procedures Act, whereas it was named in that Act's predecessor, the Hospital Provision Act. However, the Health Council assumes that government decisions on tertiary health care and tertiary preferred care will be based on a thorough assessment of the relevant

scientific aspects (as in the case of checking ‘vital interests’ for example and taking decisions on a procedure’s exit).¹¹ Partly on account of the increasing juridification of the societal reaction to government decisions and interventions (as in the case of appeal procedures), it may be important for the Health Council to contribute to the decision-making process by providing advice. More than in the past, the advice would also have to be concerned with promoting the required dynamics in the regulation of special provisions. Consultation about timely and relevant advice within the scope of this would have to be coordinated with this policy cycle.

¹¹ See Chapter 3 of the General Administrative Law Act.