Health Council of the Netherlands

To the Minister of Transport, Public Works and Water Management



Subject	: Presentation of advisory letter Fitness to drive with epilepsy	
Your reference	: VENW/DGP-2010	
Our reference	: I-508/10/CP/db/861-B	Publication no. 2010/12E
Enclosure(s)	:1	
Date	: July 22, 2010	

Dear Minister,

One of the Health Council's tasks is to advise you regarding the fitness to drive of people who have medical conditions that could affect their behaviour on the road. In line with that task, the Council recently submitted its advisory report *Fitness to drive. Proposal for some changes in the Regeling eisen geschiktheid* 2000.<sup>1</sup>

In 2009, the Commission of the European Communities decided to amend Directive 2006/126/EC of the European Parliament and of the Council on driving licences; the amendment proposals are contained in Directive 2009/113/EC (Annex A). The amendments relate mainly to Article 8 of the old directive (Directive 2006/126/EC):

'On road safety grounds, the minimum requirements for the issue of a driving licence should be laid down. (...)'

The reason for the amendment is that the minimum requirements for driving a motor vehicle differ from one member state to the next, and are not harmonised in the respects specified in the directive. Annex III, item 5, of Directive 2006/126/EC allows member states to apply stricter requirements than the European minimum requirements, but there is no scope for applying more lenient requirements. The proposed amendments relate to the rules on visual acuity, diabetes mellitus and epilepsy.

In light of the new European rules on fitness to drive and epilepsy, you asked the Health Council for advice: did the Council support the European directive with regard to epilepsy; how did the Council view the new European directive in relation to the existing Dutch *Regeling eisen geschiktheid* (Fitness Criteria Regulations; REG 2000)? In your request for advice (Annex B), you also asked the Council to obtain input from the Dutch Epilepsy Society (EVN), in order to utilise their expertise in the preparation of a response.

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### Procedure followed and structure of the advisory letter

It was originally intended that epilepsy should be addressed in the recently submitted advisory report on the general revision of REG 2000.<sup>1</sup> However, preliminary consultations indicated that the problems surrounding epilepsy and fitness to drive were sufficiently complex to warrant establishing a special expert committee to examine the topic: the Committee on Driving and Epilepsy (Annex C).

The Committee based its deliberations on the existing literature regarding fitness to drive with epilepsy.<sup>2-6</sup> The Committee met twice; a delegation of Committee members also heard a submission from a representative of the Dutch Epilepsy Society (EVN; see report, Appendix D). During the preparation of this advisory letter, there was also consultation with the *Centraal Bureau Rijvaardigheidseisen* (Driving Test Organisation; CBR) of Rijswijk, in order to gather information regarding the practical problems associated with implementation of REG 2000's existing provisions regarding epilepsy. This consultation was facilitated by the involvement of the CBR's Medical Adviser as an observer at the Committee's meetings. The draft of this advisory letter was reviewed by the Standing Committee on Medicine.

The structure of this advisory letter is as follows. First, the European proposals for amendment of the requirements regarding epilepsy and fitness to drive are described. Thereafter, the respective views of the CBR and the EVN regarding REG 2000 and their experience of its implementation are considered. The advisory letter concludes with a proposed rewording of REG 2000, Section 7 (Neurological conditions), subsection 7.2 (Epilepsy and epileptic attacks).

#### The European amendment proposals

The European proposals for amendment of the requirements are set out in point 12 of the Annex to Directive 2006/113/EC; point 12 consists of a general introduction and 14 paragraphs. The Committee makes the following observations regarding the proposals.

In a number of respects, the amended Dutch text is inconsistent with the medical terminology normally used in the Netherlands. As it stands, the wording may therefore give rise to misunderstandings (when preparing its advice, the Committee consequently made reference to the French and English versions of the document). An example of these terminological discrepancies may be found in the introduction to point 12, which refers to *'een beginnende of geïsoleerde epileptische aanval'* (literally, 'a starting or isolated epileptic attack'); the standard medical terminology is *'een eerste of initiële aanval'* (literally 'a first or initial attack'). In order to prevent

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interpretational problems, the Committee's proposed rewording includes a separate set of definitions, which is consistent with the European regulations and aligns the terminology with that normally used within the profession.<sup>7-10</sup>

At several points (12.3; 12.12 and 12.14), the European proposals include the following provision: 'National authorities may allow drivers with recognised good prognostic indicators to drive sooner.' In relation to these passages, the Committee has followed the line of the existing provisions of REG 2000 concerning the circumstances under which existing medical knowledge indicates that the prognosis is indeed good. Most significant in this regard is the Committee's proposal that, following an initial attack (or more than one attack), the disqualification period for Group 2 driving licences<sup>a</sup> should be reduced from five years to two, provided that the relevant criteria for exception are met.<sup>11</sup>

Where subsection 12.4, regarding 'other loss of consciousness', is concerned, please refer to the Health Council's advisory report published earlier this year.<sup>1</sup>

The Committee believes that the passage of subsection 12.8, regarding changes to a person's anti-epileptic therapy, which in Dutch reads '*de patiënt kan worden verzocht niet te rijden*' (literally, 'the patient may be *asked* not to drive') is too discretionary. The Committee has accordingly proposed a form of words that it considers to be more workable in practice.<sup>12-14</sup>

The Committee gave lengthy consideration to the '2% risk' referred to in subsections 12.11 and 12.14: '(...) should not be able to drive vehicles of group 2 until the epilepsy risk has fallen to at least 2% per annum.' The Committee has not been able to find any scientific evidence to indicate that such a prohibition is medically justified – particularly in view of the fact that both passages relate to circumstances in which a person does not (yet) have epilepsy at all, but there is merely an elevated risk of an attack. In relation to the particular medical pictures referred to, the Committee therefore favours giving precedence to the existing wording of section 7.6 of REG 2000, which states that the opinion of a relevant medical specialist is always required.

The Committee takes the view that stricter requirements should be made regarding professional use of Group 1 driving licences<sup>b</sup>. General advice on this matter was presented in the Health Council's advisory report published earlier this year.<sup>1</sup> For the sake of completeness, the

<sup>&</sup>lt;sup>a</sup> Group 2: licences to drive vehicles in categories C, C+E, D and D+E.

<sup>&</sup>lt;sup>b</sup> Group 1: driving licences for vehicles in categories A, B and B+E.

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relevant advice is incorporated into the Committee's proposed rewording of subsection 7.1 of REG 2000.

When formulating its proposed rewording, the Committee has sought to retain the structure of REG 2000 as far as possible, because in practice the regulations are generally considered to be clear and practicable. However, greater uniformity has been sought in the wording regarding Group 1 and 2 driving licences.

#### Input from the CBR

In the field, there is debate concerning the relevance of the EEG referred to in REG 2000, in Article 7.2.1-A and in Article 7.2.2-A and B. Debate centres mainly on the date that the EEG is made, and whether it is made before or after an attack. In its proposed rewording, the Committee has accordingly proposed making the EEG requirements more specific with regard to the date. So, for example, in a case involving two successive insults separated by an interval of more than six months, the EEG should be made after the later insult.

The Committee's proposed rewording is stricter with regard to the assessment requirements for Group 1 and 2 driving licences, insofar as the reworded regulations stipulate that an MRI scan must be performed.<sup>10,15,16</sup>

Where subsection 7.2.1-B-a is concerned, uncertainty can arise in relation to people who have had attacks both while sleeping and while awake. In such cases, the Committee proposes that at least a year should pass without the person suffering an attack while awake.<sup>17,18</sup>

Another point that can give rise to difficulties in practice is interpretation of the words 'eerste keer' ('first time') in the passage 'de eerste keer dat er een geschiktheidstermijn wordt afgegeven na goedkeuring voor rijvaardigheid' ('the first time that a period of fitness is specified after a person has been judged fit to drive'). Difficulty occurs if, for example, someone has had one or more epileptic attacks starting in 1980 but, by the time he or she first comes to the attention of the CBR (some time after 2000), has not had an attack for ten years. The Committee believes that, under such circumstances, the observation periods of one, three and five years referred to in subsections 7.1 and 7.2 of the existing REG 2000 should apply. The individual in question should be integrated into the observation regime on the basis of his or her attack history (in the example described, this would imply an observation period of five years).

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### Input from the Dutch Epilepsy Society (EVN)

During the hearing at which submissions were made by the EVN (see Annex D), a number of issues were highlighted, which EVN members often encounter in practice. Most of these issues related to the way REG 2000 is currently implemented. In line with the Health Council's statutory role, the Committee wished to concentrate on the scientific justification for the revised European regulations and on advising the Minister accordingly. However, most of the points raised by the EVN related to practical matters that do not fall within the scope of scientific assessment. The one exception was the question of periods of fitness; the Committee's proposed rewording seeks to take the fullest possible account of the EVN's wish that the rules should be based upon relevant current scientific knowledge and should be as clear as possible.

The Committee asks particularly that you give consideration to a matter that will be important at a later stage: communication regarding any future revision of REG 2000 on the basis of the Committee's advice.<sup>19</sup> The EVN indicated to the Committee that it (the EVN) was willing to play a role in that context.

# Proposed rewording of the Fitness Criteria Regulations 2000

In consideration of the matters set out above, I advise you to reword REG 2000 as follows:

Section 7. Neurological conditions 7.1 Introduction Considerations pertaining to professional use of Group 1 driving licences (codes 100 and 101)

Strict criteria must be satisfied by anyone who applies for a Group 1 driving licence for use in a professional capacity (e.g. a taxi driver, minibus driver, or someone who supervises others while driving a motor vehicle). Such people spend long periods driving and have considerable responsibility. It is therefore appropriate that they should satisfy the same criteria as people applying for Group 2 driving licences. Consequently, anyone who applies for a Group 1 driving licence who does not also satisfy the requirements for a Group 2 licence may in principle be designated fit to drive only in a private capacity.

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In specific cases, exceptions may be made, allowing a Group 1 licence to be used in a professional capacity for a period of up to five years. Such an exception may be made only if the applicant has been assessed by a specialist and if the applicant's employer has declared that the applicant will not use his/her driving licence in a professional capacity for more than four hours per day. No such exception may be made if the professional use is to involve passenger transport or the supervision of others while driving a motor vehicle.

# 7.2 Epilepsy and epileptic attacks – specialist medical report always required In the context of these regulations, 'epilepsy and epileptic attacks' covers any condition involving at least one of the following four medical pictures:

- a A first, unprovoked epileptic attack
- b Two or more unprovoked epileptic attacks in a period of less than five years
- c An acute symptomatic or provoked epileptic attack: an attack that occurs within fourteen days of a cranial brain injury, feverish illness or metabolic dysfunction or after another identifiable, causal and avoidable factor such as sleep deprivation
- d A sporadic epileptic attack: an epileptic attack historically preceded by one or more other epileptic attacks, where the interval between the most recent attack and the last prior attack is more than two years

In the implementation and interpretation of these regulations, two or more attacks occurring within a period of twenty-four hours are regarded as a single attack.

# 7.2.1 Group 1 driving licences

A. Following a first epileptic attack

Anyone who suffers a first epileptic attack is deemed unfit to drive for six months following the attack.

#### Exceptions:

- a. A first unprovoked epileptic attack, if no epileptiform or other relevant brain abnormalities are discernible on either an MRI scan or a standard electroencephalogram (EEG) undertaken after the attack: the sufferer is deemed unfit to drive for three months after the attack.
- b. A first epileptic attack associated with an underlying progressive neurological condition: individual assessment is required, but the sufferer is deemed unfit to drive for at least six months after the attack.

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c. A first, acute symptomatic or provoked epileptic attack: the sufferer is deemed unfit to drive for three months after the attack.

#### B. A history of more than one epileptic attack

Anyone who has a history of more than one epileptic attack is deemed unfit to drive for a year after the most recent attack.

#### Exceptions:

- a. Attacks associated with progressive neurological disease or with untreated epilepsy: individual assessment is required, but the sufferer is deemed unfit to drive for at least a year after the most recent attack.
- b. Sporadic attacks, where the interval between the most recent attack and the last prior attack is more than two years: the sufferer is deemed unfit to drive for six months after the most recent attack.
- c. A first myoclonic or simple partial attack immediately followed by a period of three months during which only myoclonias or simple partial attacks occur, which have no influence whatsoever on fitness to drive: the sufferer is deemed fit to drive, subject to certain limitations, as described below, under C.
- d. Only nocturnal attacks (i.e. attacks that occur while the sufferer is sleeping) for a period of one year following the first nocturnal attack: the sufferer is deemed fit to drive, subject to certain limitations, as described below, under C.

# C. Period of fitness to drive

In the first instance, the period for which a person is deemed fit to drive in accordance with the provisions of A or B, above, is one year from the date of the related assessment. Following a first re-assessment, if the person has suffered no further attacks, or if the nature of the attacks has remained limited to that described in Bb, Bc, or Bd, the person is deemed fit to drive for a further three years from the date of the assessment. Following a second re-assessment, if there has been no change in the person's condition, he or she is deemed fit to drive for a further five years; following a third re-assessment, if there has been no change in the person's condition, he or she is deemed fit to drive for a further five years; following a third re-assessment, if there has been no change in the person's condition, he or she is deemed fit to drive for a further five years; following a third re-assessment, if there has been no change in the person's condition, he or she is deemed fit to drive for a further five years; following a third re-assessment, if there has been no change in the person's condition, he or she is deemed fit to drive for a further five years; following a third re-assessment, if there has been no change in the person's condition, he or she is deemed fit to drive indefinitely.

If a person is under no obligation to report his/her condition, he or she may not come to the attention of the assessment body until five years or more after his/her most recent attack. Under such circumstances, he or she may be deemed fit to drive for five years.

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D. Reduction of medication with a view to its ultimate withdrawal, or adjustment to medication, in consultation with or on the advice of a specialist

Distinction is made as follows:

- a. The reduction of medication following an attack-free period of less than two years: the person is deemed unfit to drive while in receipt of reduced medication and for three months afterwards. Thereafter, the person is deemed fit to drive for the first period specified above, under C.
- b. The reduction of medication following an attack-free period of two years or more: the person is not deemed unfit to drive, even while in receipt of reduced medication.
- c. If, following an adjustment to or the withdrawal of medication, a person suffers an attack, he or she is deemed unfit to drive for three months, provided that the medication is readjusted in light of the attack; the person's subsequent fitness to drive is as described above, under C.

#### 7.2.2 Group 2 driving licences

#### A. Following an initial attack

Following an initial attack, the sufferer is deemed permanently unfit to drive.

#### Exception:

A single provoked or unprovoked epileptic attack, if not treated with medication and if no epilepsy-related abnormalities are discernible on any of the following: an MRI scan, a recent standard EEG and a recent EEG taken after complete or partial sleep deprivation: in view of the recognised good prognosis, the sufferer is deemed unfit to drive for two years after the attack.

#### B. Following more than one attack

Following repeated attacks, the sufferer is deemed permanently unfit to drive.

#### Exception:

Medication has been withdrawn and, following the withdrawal, no epilepsy-related abnormalities are discernible on any of the following: an MRI scan, a standard EEG, an EEG taken after complete or partial sleep deprivation and a sleeping EEG: in view of the recognised good prognosis, the sufferer is deemed unfit to drive for two years after the withdrawal of medication.

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# C. Period of fitness to drive

In the first instance, the period for which a person is deemed fit to drive on a Group 2 licence in accordance with the provisions of A or B, above, is one year from the date of the related assessment. Following a first re-assessment, if the person has suffered no further attacks, he or she is deemed fit to drive for a further three years from the date of the assessment. Following a second or subsequent re-assessment, if there has been no change in the person's condition, he or she is deemed fit to drive for a further five years.

I endorse the conclusions of the Committee. A copy of this advisory letter has been sent to the Minister of Health, Welfare and Sport.

Yours sincerely,

(signed)

Professor D. Kromhout Acting President

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### Literature

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# Annex A Directive 2009/113/EC

# COMMISSION DIRECTIVE 2009/11 3/EC of 25 August 2009 amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licences (1), and in particular Article 8 thereof,

#### Whereas:

(1)The minimum requirements for fitness to drive are not harmonised to the full extent. Member States are allowed to impose standards that are stricter than the minimum European requirements, as laid down in Annex III point 5 to Directive 2006/126/EC. (2)Since the existence of different requirements in different Member States may affect the principle of free movement the Council specifically asked for a review of the medical standards for driver licensing in its resolution of 26 June 2000. (3)In line with this Council resolution, the Commission advised that medium- and long-term work should be undertaken in order to adapt Annex III to scientific and technical progress as laid down in Article 8 of Directive 2006/1 26/EC. (4)Eye-sight, diabetes and epilepsy were identified as being medical conditions affecting fitness to drive which needed to be considered; to that end working groups comprised of specialists appointed by Member States

were set up. (5) These working groups produced reports with a view to updating the relevant points of Annex III to Directive 2006/1 26/EC. (6) Directive 2006/126/EC should therefore be amended accordingly. (7) The measures provided for in this Directive are in accordance with the opinion of the Committee on driving licences,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2006/126/EC is amended as set out in the Annex.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than one year after entry into force of this Directive. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 25 August 2009. For the Commission Antonio TAJANI Vice-President

#### Annex III to Directive 2006/126/EC is amended as follows:

 point 6 is replaced by the following: "EYESIGHT (.....)
point 10 is replaced by the following: "DIABETES MELLITUS (.....)
point 12 is replaced by the following: "EPILEPSY

12. Epileptic seizures or other sudden disturbances of the state of consciousness constitute a serious danger to road safety if they occur in a person driving a power-driven vehicle. Epilepsy is defined as having had two or more epileptic seizures, less than five years apart. A provoked epileptic seizure is defined as a seizure which has a recognisable causative factor that is avoidable. A person who has an initial or isolated seizure or loss of consciousness should be advised not to drive. A specialist report is required, stating the period of driving prohibition and the requested follow-up.

It is extremely important that the person's specific epilepsy syndrome and seizure type are identified so that a proper evaluation of the person's driving safety can be undertaken (including the risk of further seizures) and the appropriate therapy instituted. This should be done by a neurologist.

#### Group 1:

12.1. Drivers assessed under group 1 with epilepsy should be under licence review until they have been seizure-free for at least five years.

If the person has epilepsy, the criteria for an unconditional licence are not met. Notification should be given to the licensing authority.

12.2. Provoked epileptic seizure: the applicant who has had a provoked epileptic seizure because of a recognisable provoking factor that is unlikely to recur at the wheel can be declared able to drive on an individual basis, subject to neurological opinion (the assessment should be, if appropriate, in accordance with other relevant sections of Annex III (e.g. in the case of alcohol or other co-morbidity).

12.3. First or single unprovoked seizure: the applicant who has had a first unprovoked epileptic seizure can be declared able to drive after a period of six months without seizures, if there has been an appropriate medical assessment. National authorities may allow drivers with recognised good prognostic indicators to drive sooner.

12.4. Other loss of consciousness: the loss of consciousness should be assessed according to the risk of recurrence while driving.

12.5. Epilepsy: drivers or applicants can be declared fit to drive after a one-year period free of further seizures.

12.6. Seizures exclusively in sleep: the applicant or driver who has never had any seizures other than seizures during sleep can be declared fit to drive so long as this pattern has been established for a period which must not be less than the seizure-free period required for epilepsy. If there is an occurrence of attacks/seizure arising while awake, a one-year period free of further event before licensing is required (see "Epilepsy").

12.7. Seizures without influence on consciousness or the ability to act: the applicant or driver who has never had any seizures other than seizures which have been demonstrated exclusively to affect neither consciousness nor cause any functional impairment can be declared fit to drive so long as this pattern has been established for a period which must not be less than the seizure-free period required for epilepsy. If there is an occurrence of any other kind of attacks/seizures a one-year period free of further event before licensing is required (see "Epilepsy").

12.8. Seizures because of a physician-directed change or reduction of anti-epileptic therapy: the patient may be advised not to drive from the commencement of the period of withdrawal and thereafter for a period of six months after cessation of treatment. Seizures occurring during physician-advised change or withdrawal of medication require three months off driving if the previously effective treatment is reinstated. 12.9. After curative epilepsy surgery: see "Epilepsy".

#### Group 2:

12.10. The applicant should be without anti-epileptic medication for the required period of seizure freedom. An appropriate medical follow-up has been done. On extensive neurological investigation, no relevant cerebral pathology was established and there is no epileptiform activity on the electroencephalogram (EEG). An EEG and an appropriate neurological assessment should be performed after the acute episode. 12.11. Provoked epileptic seizure: the applicant who has had a provoked epileptic seizure because of a recognisable provoking factor that is unlikely to recur at the wheel can be declared able to drive on an individual basis, subject to neurological opinion. An EEG and an appropriate neurological assessment should be performed after the acute episode.

A person with a structural intra-cerebral lesion who has increased risk of seizures should not be able to drive vehicles of group 2 until the epilepsy risk has fallen to at least 2 % per annum. The assessment should be, if appropriate, in accordance with other relevant sections of Annex III (e.g. in the case of alcohol).

12.12. First or single unprovoked seizure: the applicant who has had a first unprovoked epileptic seizure can be declared able to drive once five years' freedom from further seizures has been achieved without the aid of anti- epileptic drugs, if there has been an appropriate neurological assessment. National authorities may allow drivers with recognised good prognostic indicators to drive sooner.

12.13. Other loss of consciousness: the loss of consciousness should be assessed according to the risk of recurrence while driving. The risk of recurrence should be 2 % per annum or less.

12.14. Epilepsy: 10 years freedom from further seizures shall have been achieved without the aid of antiepileptic drugs. National authorities may allow drivers with recognised good prognostic indicators to drive sooner. This also applies in case of "juvenile epilepsy".

Certain disorders (e.g. arterio-venous malformation or intra-cerebral haemorrhage) entail an increased risk of seizures, even if seizures have not yet occurred. In such a situation an assessment should be carried out by a competent medical authority; the risk of having a seizure should be 2 % per annum or less to allow licensing. EN 26.8.2009 Official journl of the European Union L 223/35.

# Annex B Request for advice

Following on from the request for advice made by the Minister of Transport, Public Works and Water Management on 17 July 2007, the General Secretary to the Health Council received the following request for advice regarding fitness to drive and epilepsy from of the Ministry of Transport, Public Works and Water Management on 17 May 2010 (letter no. VENW/DGM0-2010/4520).

Dear Mrs Wijbenga,

Following our recent discussions and your offer to report on fitness to drive and epilepsy, I am writing to request that you advise me on this matter.

The relevant European directive is dated 25 August 2009 and must therefore be implemented no later than 25 August 2010. Consequently, I wish you to advise me no later than late June or early July. For the directive to be implemented on time, at least six weeks are required following receipt of your advice, partly because of the need for the CBR to review the practicability of the changes.

As we discussed, I also wish you to make contact with the Epilepsy Society in order that its expertise may be utilised in the preparation of your advice. I nevertheless consider the Health Council solely responsible for formulation of the advice.

In your response, please indicate whether the Health Council supports the content of the European directive on epilepsy.

Any further consultation on this matter should be directed through Mr J. van der Vlist at my ministry. Kind regards,

THE DIRECTOR-GENERAL FOR MOBILITY On behalf of

THE MINISTER OF TRANSPORT, PUBLIC WORKS AND WATER MANAGEMENT

Annex C The Committee

- Professor J.J. Heimans, *chairman* Professor of Neurology, VU Medical Centre, Amsterdam
- R.A. Bredewoud, *observer* physician, Head of the Medical Department, Driving Test Organisation, Rijswijk,
- Dr J.A. Carpay neurologist, Tergooi Hospitals, Blaricum
- Dr C.A. van Donselaar neurologist, Maasstad Hospital, Rotterdam
- Dr M.C.T.F.M. de Krom neurologist, University Medical Center, Maastricht
- Dr C.A. Postema, physician, *secretary* Health Council, The Hague

The Health Council and interests

Members of Health Council Committees – which also include the members of the Advisory Council on Health Research (RGO) since 1 February 2008 – are appointed in a personal capacity because of their special expertise in the matters to be addressed. Nonetheless, it is precisely because of this expertise that they may also have interests. This in itself does not necessarily present an obstacle for membership of a Health Council Committee. Transparency regarding possible conflicts of interest is nonetheless important, both for the President and members of a Committee and for the President of the Health Council. On being invited to join a Committee, members are asked to submit a form detailing the functions they hold and any other material and immaterial interests which could be rel-

evant for the Committee's work. It is the responsibility of the President of the Health Council to assess whether the interests indicated constitute grounds for non-appointment. An advisorship will then sometimes make it possible to exploit the expertise of the specialist involved. During the establishment meeting the declarations issued are discussed, so that all members of the Committee are aware of each other's possible interests.

# Annex D Hearing report

Report on the hearing to take a submission from a representative of the Dutch Epilepsy Society (EVN), held on 15 June 2010, at the Clara Unit of the Maasstad Hospital, Rot-terdam

#### Present:

- Dr C.A. van Donselaar, neurologist, member of the Committee on Driving and Epilepsy
- A.W. Tempels, CEO of EVN
- Dr C.A. Postema, physician, Secretary at the Health Council (report author)

Postema explained the purpose of the gathering. The Ministry of Transport, Public Works and Water Management had asked the Health Council for advice regarding the new European regulations in relation to the existing Fitness Criteria Regulations 2000 (REG 2000). The ministry's views should be considered. In recognition of the Health Council's role as an independent advisor, the meeting formally had the status of a hearing.

Tempels indicated that the existing REG 2000 regime was satisfactory in practice. Nevertheless, on the basis of the experiences of EVN members, there were a number of matters that he wished to draw to the Committee's attention:

• It is often not clear to epilepsy sufferers what the application and assessment process entails. Who should notify the authorities about their condition, and when? The peo-

ple affected fall into two groups: people with epilepsy who want to get a driving licence and existing drivers who develop epilepsy. For safety reasons, the EVN highlights the risks associated with using the roads on its website and in the context of telephone contact; REG 2000 is explained as and when the need arises, and written information is made available.

- The rules on assessment are not always clear. Can one be assessed by s neurologist, for example?
- The cost of the assessments required under REG 2000 is resented by many.
- The EVN has questions regarding the periods of fitness to drive proposed in the new European regulations. The periods specified in the existing REG 2000 are clear. Van Donselaar indicated that the Committee was looking into that particular matter; it certainly embraced the principle that the periods should be defined as clearly as possible.
- The EVN enquired about the communication concerning the new regulations. Who was responsible? The Dutch Neurology Society; the Ministry; the CBR; the Health Council? The EVN is willing to play a role in this context. Van Donselaar indicated that the Committee was indeed considering the question of communication.
- The EVN asked the Committee to consider the role of medication. The regulatory changes introduced in December 2008 were a source of concern for many people, although a workable situation had since developed in practice.