Gezondheidsraad

Health Council of the Netherlands

To the Minister of Infrastructure and the Environment ((I&M)

Subject	: Presentation of advisory letter *Fitness to Drive with Epilepsy*
Your reference	: IENM/BSK-2011/176176
Our reference	: I-1152/12/CP/cn/861-E Publication no. 2012/08E
Enclosure(s)	: 4
Date	: May 22, 2012

Dear Minister,

On 7 January 2012 I received a request from you to provide my vision on the knowledge status surrounding the professional use of a driving licence by people with epilepsy. You were under the impression that the current Regulation Suitability Requirement 2000 (REG2000) was more stringent than required by the European legislation. You asked for a re-evaluation of the requirements for the professional use of the group 1 driving licence (Annex A).

I therefore decided to appoint a special committee of experts (Annex B) to answer this request for advice. In appointing this Committee, I focused specifically on expertise in the field of European legislation.

This Committee evaluated the matter and held a hearing together with the Epilepsy Association of the Netherlands (Annex C). The medical advisor of the Statistics Netherlands (CBR) participated as an advisor in the consultations of the Committee. The Committee used the existing literature about fitness to drive with epilepsy as a starting point.

The advisory letter from the Health Council on *Fitness to Drive with Epilepsy* was published in 2010.[1] The reason for this advice was the decision in 2009 by the Commission of the European Communities to amend Directive 2006/126/EC of the European Parliament and the Council concerning the requirements for the driving licence of people with epilepsy, among others. You amended the REG2000 based on the abovementioned advice from the Health Council.

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The current legislation for epilepsy

The text of the current REG2000 concerning epilepsy has been included in Annex D. The request for advice pertains specifically to the passage:

Stringent requirements must be enforced on the professional use of a group 1 driving licence by people with epileptic seizures. People with epileptic seizures who meet the requirements set below for group 1, but who do not also meet the requirements for group 2 as formulated below, can only be deemed fit to drive if the driving licence is limited to private use.

An exception can be made – in individual cases – to this limitation to private use following a special request. These individuals can be declared fit for limited professional transportation for a period of five years, excluding the transportation of people, or the driving of third parties under supervision, for a maximum of four hours per day. Conditions include a medical examination by a neurologist and an employer's declaration according to the CBR template.

This passage was added with the amendment in 2010, taking into consideration the general systems of the REG2000 and the insights at the time. Following the medical examination by the neurologist and the employer's declaration, the driving licence is assigned a so-called 'code 101', which means that the abovementioned limitation applies. The general underlying thought is that limiting the driving duration per day (the 'exposure') will reduce the risk of accidents.

Risk assessment in traffic

The generally applied formula for calculating safety risks is the product of *chance* (a) times *effect* (b) times *exposure* (c).

a *Chance*. The concept of relative risk is used for risk assessments in traffic. In the formula to calculate the relative risk, the 'chance' consists of the extent to which a group of people with a certain characteristic (for example age, alcohol level or disease) has an increased risk of an accident compared to a group of people without this characteristic.

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The other variables that play a role are:

b *effect*: the number of additional accidents that the group with this characteristic causes and the severity of these accidents

c *exposure*: the time that someone spends behind the wheel.

Concerning the severity of the accidents: various statistics show that – in general – the driver himself/herself is the victim of the accident in just over 60 % of the accidents. His/her passenger(s) is/are the victim(s) in approximately 25 % of the accidents. In the other cases the victims are other people. Of all the accidents with physical injury, 3 % are fatal.

The relative risk is known for many characteristics in traffic. For example, it is known that the risk of an accident in young men (16-19 years) compared to men aged 45-54 years produces a relative risk of 5.35; in other words: a clearly increased risk.

The working group 'Epilepsy and fitness to drive' of the European Union also used the formula for calculating the relative risk in drafting the European legislation. There was consensus among the participants for this.[2] Inherent in the use of relative risks is that a certain level of risk is accepted. The term relative risk provides a numerical insight into the risks, but only takes the subjective social consequences into consideration to a limited extent. There is a subjective difference whether someone becomes the victim of an accident through his/her own fault or someone else's fault. A relative risk expresses the objectively increased risk of damage, but does not rule out innocent victims.

Relative risk and epilepsy

In creating the European legislation in 2006, it was determined that a relative risk up to 3.0 was acceptable for epilepsy in traffic.[2,3] What does this mean for the limitations that should apply for epilepsy patients in the Netherlands?

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The risk of an epileptic seizure is greatest during the first year after discovery of the illness and decreases over time. The risk of a new seizure also depends on the type of epilepsy. Figures about this are available from various international studies. These data can serve as a basis for the calculation of the relative risk.

The REG2000 distinguishes between two types, namely the type in which only '*a first epileptic seizure*' occurs and the type in which several epileptic seizures are experienced: '*epilepsy*'.

Following the first seizure, the relative risk for a group of treated individuals eighteen months after the seizure is 2.7 with four hours average driving time per day. With five hours average driving time per day, the relative risk for this group is 3.2.4-6 As the risk of a new seizure decreases over time, the relative risk after two years will be lower than after eighteen months. For the average group of *individuals with epilepsy*, the relative risk after two years free of seizures is 2.2.[4,6]

Opinion

Firstly, it must be concluded that there is always a link between the risk of an accident and the duration that someone is present on the road as a driver.[7] This principle is maintained in various articles in the REG2000 for the professional use of a group 1 driving licence and is inherent to the system maintained in our country. Historically, the duration for the limited professional use of the group 1 driving licence has been set at a maximum of four hours.

The Committee has extensively evaluated the significance of the four-hour criterion in relation to the REG2000. In that respect, the Committee deems it necessary not to deviate from the system used in Europe and concludes that the four-hour maximum used in the Netherlands relates to this quite reasonably. In other words: there are no reasons to maintain the presumption that the Netherlands maintains more stringent standards. There may be differences in execution between the member states (for example, Sweden has an obligation to report for doctors), but in general the rules are similar at an outcome level.

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An important difference in the method used by the European working group compared to the current Dutch legislation is that they use an *average* driving time per day calculated over seven days per week instead of a *maximum* driving time per day.

Implementation in practice and the hearing with the Epilepsy Association of the Netherlands have shown that obtaining the employer's declaration is the main problem. Obtaining this declaration can lead to conflicts between the employer and employee and causes issues concerning privacy.

Proposal

A solution for the existing practice can be found, based partly on recent literature, by using the average criterion instead of the *maximum* criterion. The Committee is of the opinion that such a change will not have any negative consequences for general traffic safety, taking into consideration the system of relative risk. However, this does increase the possibility for professional use. One important condition is that it must be clearly communicated in the consultation room and in information material that the four hour average relates to the total of *professional and private* use and that this average applies over seven days per week.

A number of aspects warrant closer consideration in such an approach. A possible objection to such a proposal might be that a relationship could occur between the duration of time behind the wheel and an increased risk of an epileptic seizure caused by fatigue. However, the Committee is of the opinion that this is not the case based on existing scientific knowledge. This objection therefore becomes invalid. Of course the usual pieces of advice in practice, such as driving for two hours and resting for fifteen minutes, also apply to drivers with epilepsy.

A second objection that could be raised is that the implementation of the average criterion could result in a decreased legal status for an individual employee. This applies particularly if his/her employer has assignments further away, which would result in the combination of commuting and professional driving exceeding the average of four hours.

The hearing with the Epilepsy Association of the Netherlands (EVN) aimed to determine how the EVN feels about this. The EVN is of the opinion that abolition of the code 101 is preferable and

has no objections to using the average principle. Formulated in this way, this means that the abovementioned proposal meets both the desire for safety and the desire to match the European legislation and the individual responsibility. An additional advantage is that the implementation of the REG2000 will become simpler and cheaper.

The approach with the use of the average criterion means that there is a theoretical curtailment compared to the current legislation concerning the private use of the driving licence. However, the Committee is of the opinion that this will not result in practical consequences as a maximum of 28 hours driving time per week is permitted.

Time limit

The Committee has considered maintaining the time limit for the limitations imposed. Based on the data presented above about the relative risks of epilepsy, the Committee concludes that the limitation advice may be lifted two years after the last seizure. This is the case if there have been no further seizures and no other relevant abnormalities are found during medical examination by a neurologist. The time limit of two years applies both to people who have experienced a first epileptic seizure and to epilepsy patients. After all, the relative risk for both groups after two years and with a driving time of less than an average of four hours per day is lower than the relative risk of 3.0 accepted by the European legislation.

Permanent limitation for transport of people and driving under supervision

Taking into consideration the abovementioned system of relative risk, the Committee deems it essential to maintain the limitation on transport of people or driving under supervision (as is the case, for example, for a driving instructor). Lifting this limitation would entail accepting a higher resulting damage, such as severe or fatal injury to passengers and/or fellow road users. A consequence of implementing this advice could be that a new code needs to be implemented.

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Advice

This brings the Committee to advise in response to your request for advice that – in chapter 7.2 of the REG2000 – the passage that mentions the limitations on the professional use of a driving licence should be formulated as follows:

Limitations must be applied to both the private and professional use of a group 1 driving licence by people with epileptic seizures. These drivers should be advised to limit the driving time to less than four hours per day calculated over seven days per week. If the person is seizure-free, this limiting advice may be lifted two years after the last seizure. The professional transportation of people, or driving under supervision remains prohibited.

The advice was tested by the Standing Committee on Medical of the Health Council. I support the findings in the advice by the Committee.

Yours sincerely,
(signed)
Professor H. Obertop
Acting President

Literature

1 Health Council of the Netherlands. Advisory letter Fitness to drive with epilepsy. The Hague: Health Council of the Netherlands, 2010; 2010/12E. .

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4 Manford M, Hart YM, Sander JW, Shorvon SD. National General Practice Study of Epilepsy (NGPSE): partial seizure patterns in a general population. Neurology 1992; 42(10): 1911-1917.

5 van Donselaar CA, Habbema JD. Recurrence after first seizure. Lancet 1991; 337(8732): 46.

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7 Sorajja D, Shen WK. Driving guidelines and restrictions in patients with a history of cardiac arrhythmias, syncope,or implantable devices. Curr Treat Options Cardiovasc Med 2010; 12(5): 443-456.

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Annex **A**

The request for advice

On 7 January 2012, the President of the Health Council received the following request for advice from the Minister for Infrastructure and the Environment, concerning the request for advice about driving licence with epilepsy (letter no. IENM/BSK-2011/176176).

Dear Ms Gunning,

I would like to receive your vision on the current state of knowledge surrounding the professional use of a driving licence with epilepsy. The Regulation Suitability Requirements 2000 (REG2000) was amended for epilepsy in 2010. I have the impression that this amendment has unintentionally resulted in a tightening that has no foundation in a European directive. I therefore ask you to reconsider your advice on the setting of stringent requirements for the professional use of a group 1 driving licence (code 100 and 101).

I would like to receive your advice by the end of February 2012 about the limitation concerning professional driving with epilepsy included in the regulation in 2010. If you see a need for it, I would also like to receive a text proposal for the regulation.

For questions concerning this request for advice, please contact Ms S. Faber, Tel.: 070-4567124

Yours sincerely,
the Director of Roads and traffic safety
M.C.A. Blom

Annex **B**

The Committee

- Prof. J.J. Heimans, *chairman*
  Professor of Neurology, VU Medical Centre, Amsterdam
- Dr. J.A. Carpay
  Neurologist, Tergooi Hospitals, Blaricum and Leiden University Medical Centre, Leiden
- Dr. C.A. van Donselaar
  Neurologist, Maasstad Hospital, Rotterdam
- Dr. M.C.T.F.M. de Krom
  Neurologist, Maastricht University Medical Centre, Maastricht
- Dr. E. Schmedding
  Neurologist, University Hospital Brussels, Brussels
- R.A. Bredewoud, Physician, *advisor*
  Head of the Medical Department, Driving Test Organisation, Rijswijk
- Dr. C.A. Postema, Physician, scientific *secretary*
  Health Council, The Hague

The Health Council and interests

Members of Health Council Committees 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 inter-

est is nonetheless important, both for the chairperson 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 relevant 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 inaugural meeting the declarations issued are discussed, so that all members of the Committee are aware of each other's possible interests.

Annex **C**

Report from the hearing

with the Epilepsy Association of the Netherlands (EVN), held on 13 March 2012 at the Health Council in The Hague.

Present:

- Dr. C.A. van Donselaar, Neurologist, member of the Committee on Fitness to Drive with Epilepsy
- A.W. Tempels, Director Epilepsy Association of the Netherlands
- Dr. C.A. Postema, Physician, Health Council secretary (report)

Postema defined the aim of the meeting. The Minister of Infrastructure and the Environment has asked the Health Council to advise on the Regulation Suitability Requirement 2000 (REG2000) in relation to epilepsy. The Minister is under the impression that the amendment from 2010 has resulted in a tightening of the regulation that does not have any foundation in the European legislation.

Tempels indicated that the current REG2000 does not function to a satisfactory level. Since the implementation of the code 101 in 2010, various signals have been received from members of the EVN that they cannot work with the regulation. There have even been cases of dismissal and various court cases have been conducted.

Van Donselaar and *Postema* provide background information and the fairness of the 4-hour criterion. The Netherlands has not fallen out of step. For example, contrary to the Netherlands, other countries have an obligation to report. A possible solution could be

found by working with an average instead of the maximum. The use of code 100/101 can then expire, provided that thorough information is provided.

Tempels suspects that the EVN will accept such a solution. The disappearance of code 100/101 will take the sting out of the problem. In theory, the EVN supports the responsible use of a driving licence and that entails that adequate legislation must be provided.

Van Donselaar and *Postema* mention that a possible objection could be that an individual employee could exceed the 4-hour average driving time if the work area is changed. The average 4-hour criterion is also in agreement with the European vision and recent scientific literature. The committee is divided about the time limit that should be enforced: 2 years or 5 years.

All participants endorse the importance of thorough information provided to the target group.

Annex **D**

Regulation Suitability Requirement 2000 (REG2000)

Chapter 7. Neurological conditions

7.1. Introduction

This Chapter formulates the requirements for the fitness concerning the subject ‘neurology’, including those for epilepsy.

7.2. *Epileptic seizures and epilepsy*

A specialist report, composed by a neurologist, is required for the evaluation of the fitness of people with (a history of) epileptic seizures. The standards from paragraph 7.5 and 7.6 also apply for arteriovenous malformations, intracerebral haemorrhages, cerebral infarctions and brain tumours with the risk of epileptic seizures.

People in possession of a driving licence who develop epilepsy are unfit for an unlimited driving licence.

Stringent requirements must be enforced on the professional use of a group 1 driving licence by people with epileptic seizures. People with epileptic seizures who meet the requirements set below for group 1, but who do not also meet the requirements for group 2 as formulated below, can only be deemed fit to drive if the driving licence is limited to private use.

An exception can be made – in individual cases – to this limitation to private use following a special request. These individuals can be declared fit for limited professional transportation for a period of five years, excluding the transportation of people, or the driving of third parties under supervision, for a maximum of four hours per day. Conditions include a medical examination by a neurologist and an employer's declaration according to the CBR template.

The following departure points apply for the standards in paragraph 7.2:

- Epilepsy: a person is said to have epilepsy if he/she has had two or more non-provoked epileptic seizures in a period of less than five years.
- Provoked epileptic seizures (or an acute symptomatic seizure): an epileptic seizure that occurs within 14 days of injury to the brain or skull, a febrile illness, a metabolic disruption, or any other identifiable causal and avoidable factor, such as sleep deprivation.
- Sporadic epileptic seizure: an epileptic seizure in a person with a history of one or more epileptic seizures, but with an interval of more than two years between this seizure and the last seizure.

Several seizures within 24 hours are considered as a single seizure.

7.2.1. First epileptic seizure

a group 1: People with a first epileptic seizure are not fit for a group 1 driving licence up to six months after the seizure.

Exceptions:

- a first non-provoked epileptic seizure without 'epileptiform abnormalities' on the standard EEG (recorded after the seizure) and without abnormalities relevant to epilepsy on the MRI scan of the brain: not fit for three months after the seizure;
- a first provoked epileptic seizure: not fit for at least three months after the seizure, partially dependent on the cause of the seizure;
- a first epileptic seizure with a progressive neurological condition: to be evaluated by the neurologist on an individual basis, but not fit for at least six months after the seizure.

At the end of the seizure-free period, these people can be deemed fit for a period of one year based on a specialist report, composed by a neurologist. If the person remains seizure-free, the maximum fitness time-limit is then three years, then five years and then unlimited.

Those in possession of a driving licence who are already seizure-free for three years or more by the time of a first evaluation by the CBR may be declared fit for a period of three years immediately, those who have been seizure-free for more than five years can be declared fit for a period of five years.

b group 2: People with a first – provoked or unprovoked – epileptic seizure are permanently unfit for a group 2 driving licence.

Due to the recognised favourable prognosis, an exception can be made for people who have remained seizure-free for two years and who were not treated with anti-epilepsy medication during this period. They can be declared fit if there are no abnormalities relevant to epilepsy on the MRI scan of the brain, on a recent standard EEG and on a recent EEG following partial or complete sleep deprivation.
At the end of the seizure-free period, these people can be deemed fit for a period of one year based on a specialist report, composed by a neurologist. If the person remains seizure-free, the maximum fitness time limit is then three years, followed by repeated periods of five years.

Those in possession of a driving licence who are already seizure-free for five years or more by the time of a first evaluation by the CBR may be declared fit for the maximum period of five years immediately.

7.2.2. More than one epileptic seizure in the history (epilepsy)

a group 1: People with a history of more than one epileptic seizure are not fit for a group 1 driving licence up to one year after the last seizure.

Exceptions:

- a sporadic epileptic seizure: not fit for six months after the sporadic seizure;
- epileptic seizures with a progressive neurological condition: to be evaluated by the neurologist on an individual basis, but not fit for at least one year after the last seizure.
- seizures during sleep: a person becomes fit if it becomes evident that seizures only occur during sleep during the first year after the first seizure during sleep;
- myoclonic and simple partial seizures: a person becomes fit if it becomes evident that only myoclonic or simple partial seizures have occurred – that do not affect the fitness to drive a motor vehicle – during the first three months after the first myoclonic or simple partial seizure.

The people that meet these conditions can be deemed fit for a period of one year based on a specialist report, composed by a neurologist. If the situation remains the same, the maximum fitness time-limit is then three years, then five years and then unlimited.

Those in possession of a driving licence who are already seizure-free for three years or more by the time of a first evaluation by the CBR may be declared fit for a period of three years immediately, those who have been seizure-free for more than five years can be declared fit for a period of five years.

b group 2: People with a history of more than one epileptic seizure are permanently unfit for a group 2 driving licence.

Due to the recognised favourable prognosis, an exception can be made for people who have remained seizure-free for five years and who were not treated with anti-epilepsy medication during this period. They can be declared fit if there are no abnormalities relevant to epilepsy on the MRI scan of the brain, on a recent standard EEG and on a recent EEG following partial or complete sleep deprivation.

At the end of the seizure-free period, these people can be deemed fit for a period of one year based on a specialist report, composed by a neurologist. If the person remains seizure-free, the maximum fitness time limit is then three years, followed by repeated periods of five years.

Those in possession of a driving licence who are already seizure-free for five years or more by the time of a first evaluation by the CBR may be declared fit for the maximum period of five years immediately.

7.2.3. Change or reduction in anti-epilepsy medication

The following applies to any change or reduction in the anti-epilepsy medication in consultation with or as advised by the treating physician:

- when reducing the anti-epilepsy medication after a seizure-free period of less than two years, the person becomes unfit for a group 1 driving licence for the period of dose reduction and until three months after stopping the medication;
- when reducing the anti-epilepsy medication after a seizure-free period of two years or more, the person does not become unfit for a group 1 driving licence, even during the period of dose reduction;
- If an epileptic seizure occurs during the change or reduction of the anti-epilepsy medication, the person becomes unfit for a group 1 driving licence for three months, provided that the medication is adjusted immediately, otherwise the normal seizure-free periods from paragraph 7.2.1 and 7.2.2 apply.

7.3. Consciousness disorders (other than epilepsy)

People with consciousness disorders – with the exception of the consciousness disorders listed in paragraphs 7.3.1 and 7.3.2 – are unfit for all driving licences (see also paragraphs 6.9 and 8.5). A specialist examination is not required if the consciousness disorder does not form part of the recent patient history and if notes by the examining physician also state that further specialist examination did not reveal any causes. In all other cases, a specialist report is required for the evaluation of fitness.

The person can be declared fit to drive for a group 1 driving licence if he/she has been free of these disorders for at least one year. The fitness period is then extended to five or ten years, depending on the severity of the condition. These people are not fit for a group 2 driving licence, except if the consciousness disorder has not been experienced during the last five years; in that case the person is declared fit for a period of five years.