

CIECA Report Medical Fitness to Drive Sleep apnoea and narcolepsy

Report covering the answers to the questionnaire
about medical fitness to drive and sleep apnoea and narcolepsy
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CIECA Topical Group on Fitness to Drive
Sub group 2: Setting Standards for the Evaluation of Medical Fitness to Drive
Witold Pisarek, Sara Magnusson & Åsa Ericson

CIECA Secretariat
Avenue de Tervueren 36-38 | 1040 Brussels | info@cieca.eu

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1. INTRODUCTION

This report summarizes the answers in the questionnaire regarding “Sleep apnoea and narcolepsy” which was sent to 31 countries within Europe. The questionnaire was answered by 15 countries, although some of the countries did not answer all the questions. Some of those countries which did not answer all the questions, or where the answers needed clarification were contacted again. In 2 cases new answers or clarifications were received. Sixteen of the invited countries did not answer the questionnaire at all.

Responses were received from Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Ireland, Lithuania, Luxemburg, Norway, Portugal, Spain and Sweden.

Eight main questions were asked and 2 of them contained sub-questions.

2. SUMMARY OF RESPONSES

Question 1. How is sleep apnoea notified to the authority in your country?

Question answered:

14 countries responded

There was a big variation of regulations and praxis in how sleep apnoea is notified to the authority in the different countries that answered the questionnaire. In some countries, the doctors do not report unfit drivers to the authority at all except special cases. Instead they have only a duty to inform the patients themselves who in turn are obliged to notify the authority. In most countries, the authorities who are responsible for assessment of fitness to drive acquire knowledge about unfit drivers on basis of incoming medical certificates. Only 3 countries stated that the doctors have a (legal) duty to notify unfit drivers to the authority.

Details:

- In some countries there are several ways of notifying sleep apnoea to the authority
- In 3 countries the doctors have to report drivers with sleep apnoea who do not meet the requirements to the authority
- In 1 country the notification occurs also by the doctors but it is unclear if the notification is mandatory
- 4 countries use self-declaration by the applicant but it is unclear if for both group 1 and 2 drivers
- In 4 countries the doctors issue a medical certificate and in 1 country the drivers are screened for sleep apnoea at the driver’s assessment center
- In 2 countries the Police can notify to the authority when the driver causes an accident, behave unusual in the traffic or if there is any other information about the driver that the Police want to notify the authority about
- In 3 countries the doctors inform the patients that they are unfit to drive but do not report the drivers the authority

Question 2. Under which conditions are drivers with sleep apnoea allowed to hold the licence?

Question answered:

All 15 countries responded

There was a big variation among the responding countries regarding the conditions under which drivers with sleep apnoea may hold a licence. Some of the answers related strictly to the medical requirements while other countries report how the administrative procedures are constructed and performed. In most countries, the medical criteria involve adherence to the treatment, good treatment effect as well as amelioration of daytime sleepiness and regular medical review. Two countries answered more generally that the licence may be held when the traffic safety is not compromised, and the drivers are able to drive safely.

Details:

The countries responded in different ways and with different combination of criteria regarding when the licence may be hold:

- 1 country answered when the drivers do not suffer from excessive sleepiness independently of grade of sleep apnoea
- In 4 countries, if they have moderate or severe sleep apnoea with daytime sleepiness provided that the following has been assured in various combinations (not all criteria in all countries):
 - good symptom control or adequate control of the condition
 - good treatment effect
 - periodic medical review
 - no functional disability
 - improvement of sleepiness
- 1 country answered that doctor's approval is mandatory
- In 1 country in drivers with mild daytime sleepiness (AHI < 15) an assessment is done individually by the doctors
- In 1 country, medical expert at the authority decides, occasionally based on additional medical certificate
- 2 countries specified that EES (Epworth sleepiness scale) has to be under 10 to hold the licence
- In 2 countries there are more general formulations, e.g. the drivers may hold the licence when traffic safety is not compromised or the drivers are able to drive safe
- In 1 country the licence may be hold for group 1 drivers with no daytime sleepiness and for group 2 drivers when a good treatment effect is achieved with no daytime sleepiness
- 1 country answered that holding the licence has to be in accordance with the EU directive

Question 3. How do you investigate this?

Question answered:

All 15 countries responded

In most countries the investigation of fitness to drive, when it comes to sleep apnoea, is performed by medical specialists or specially approved doctors using a sleepiness scale, apnoea-hypopnoea index and other special tests.

Details:

- Many countries answered that the investigation is done by medical specialists/practitioners using among others EES (Epworth sleepiness scale) and apnoea-hypopnoea index (AHI) as well as wakefulness tests and apnoea tests
- In 1 country the medical expert in the authority makes the decision after a medical assessment/certificate
- In 1 country specially approved doctors assess medical fitness to drive. On their request an investigation in sleep lab can be performed
- In 1 country clinical assessment for group 1 drivers is performed without specific tests and for group 2 drivers good compliance to CPAP treatment and AHI < 15 is required

- In 1 country the doctors are responsible for investigation and has a duty to notify the authority. If circumstances are still unclear the authority overtake the investigation and request a medical opinion to determine if the road safety is compromised

Question 4. Do you have specific regulations for narcolepsy or other central disorders of hypersomnolence (idiopathic hypersomnia, Klein-Levin syndrome)?

Question answered:

14 countries responded

Regarding specific regulations for narcolepsy or other central disorders of hypersomnolence, most countries declare having such regulations. Unfortunately only 10 of 14 countries specified which conditions the specific regulations concern. Since some of the countries answered that the specific regulation concerns also sleep apnoea and cataplexy it is likely that the question could have been more detailed to avoid misunderstanding since the meaning of the questions was only to list possible specific regulations for narcolepsy or other central disorders of hypersomnolence.

Details:

- 6 countries answered YES; answers were not specific but most often the specific regulations concerned narcolepsy
- 5 countries answered NO
- 2 countries answered YES with clarifications that the regulations only generally mention conditions which affect wakefulness
- 2 countries ticked both the YES and NO responses and thus their response was invalid.

Question 4.a. Which diseases are covered by the specific regulations?

Question answered:

10 countries responded

Most countries listed one or more of the following diseases: narcolepsy, cataplexy, other sleep and alertness disturbances, primary/central hypersomnias, Klein-Levin syndrome and roncopathy.

Question 4.a.1. Do the regulations differ for driving licences in group I and II?

Question answered:

12 countries responded

The vast majority of countries stated that the regulations differ for driving licences in group 1 and 2 and the main difference is related to review periods. However, two countries declared that narcolepsy is an obstacle only for group 2 drivers.

Details:

- 10 countries answered YES and some countries provided the following comments:
 - 2 countries answered that there is different medical review periods for group 1 and group 2 and one of those countries mentioned that there are stronger regulations for group 2 concerning treatment effect
 - 2 countries said that narcolepsy is always an obstacle for group 2

- Another country answered that for group 1 drivers with narcolepsy the following is required: good treatment effect and compliance as well as symptom free period of 6 months; for group 2 drivers with narcolepsy with cataplexy a driving licence may not be issued or renewed
- 2 countries answered NO even if in 1 of them doctors can be stricter in assessment for group 2

Question 4.b. Do the regulations require that assessment of medical fitness includes subjective or objective parameters or both? If so, which ones?

Question answered:

13 countries responded

Majority of countries answered that the regulations require objective and subjective parameters for narcolepsy or other central disorders of hypersomnolence. The answers included a mixture of parameters such as AHI (Apnoea Hypopnoea Index), daytime sleepiness, treatment compliance and control of the disease. Answers from a majority of countries discussed both sleep apnoea, narcolepsy and other central disorders of hypersomnolence, i.e. not only narcolepsy or other central disorders of hypersomnolence as mentioned in all sub questions 4 a, b, c, d. Even here it is likely that the question was misunderstood on the part of responding countries.

Details:

- 4 countries answered that NO parameters at all are required for the assessment
- According to another country the methods are not described in regulations and it is up to doctors to choose
- 8 countries answered that BOTH subjective and objective parameters are required, for instance Osler test, daytime sleepiness, compliance, control of the disease
- In 1 country only objective parameters (AHI) are required

Question 4.c. Do the regulations cover the use of any medication for narcolepsy?

Question answered:

12 countries responded

The answers on the question if the regulations cover the use of any medication for narcolepsy were almost equally divided between 'yes' and 'no' responses. Thus, one cannot rule out that for many countries it was unclear if the question included sleep apnoea or only narcolepsy and other central disorders of hypersomnolence. This because some countries indicated in its answer a medication against sleep apnoea. Some countries answered the question without any additional comments. The response pattern recorded for this question suggests that almost half of the respondents did not understand the question well enough to provide a rational response.

Details:

- 5 countries answered both YES and NO and the answers were mostly unclear
- 7 countries answered NO.

Question 4.d. Do the regulations also specify frequency of follow ups?

Question answered:

12 countries responded

Regarding frequency of follow-up, the majority of the responding countries (8) reported that their regulations do specify the frequency of follow-ups. 4 countries has 3 or sometimes up to 5 years review periods for group 1 drivers and 1 year for group 2. Some countries do not have any difference between group 1 and 2 drivers. Only 1 country answered that for narcolepsy there is a review period of 1 year. The answers indicate that the majority of the respondents meant sleep apnoea in their answers while the question in fact was aimed only at narcolepsy and other central disorders of hypersomnolence. This suggests that it is likely that the question was misunderstood by some the responding countries.

Details:

- 8 countries answered YES and the following comments were provided:
 - 4 countries answered that for group 1 drivers the frequency of follow ups is 3(-5) years and 1 year for group 2
 - 2 countries answered 2 years for both groups
 - 1 country answered 3 years or individually depending on illness severity or regular medical review
 - In 1 country the regulations concern narcolepsy drivers who are allowed to drive with follow ups every year
- 5 countries answered NO

Question 5. Do you have any suggestions for what a relevant regulation for narcolepsy and/or other central disorders of hypersomnolence should include?

Question answered:

10 countries responded

Majority of the countries did not have suggestions what a relevant regulation for narcolepsy and/or other central disorders of hypersomnolence should include or declare that the actual regulations are suitable. Some of those countries are sceptical of more specific regulations, for instance because of the risk of not being able to take personal circumstances into account. Suggestions from 3 countries include the possibility to confirm satisfactory disease control by a doctor, more functional criteria and more exact criteria to issue the licence and when the condition is to be regarded as effectively treated.

Details:

- 2 countries answered that there is no need to change, the regulations are suitable
- 4 countries do not have any suggestions
- 1 country answered that it can be dangerous to have specified methods because they can reduce the possibility to take into account personal situations; the functional consequences should be stressed more than physiological parameters
- 1 country declares that common European rules should be helpful
- 1 country sees need of more exact criteria when driving licences may be issued or renewed and when the medical conditions are to be regarded as effectively treated
- Another country advocates that confirmation of satisfactory control can be done by the treating clinician
- 1 country is of the opinion that the regulations should leave to the doctor to judge which parameters to use for the assessment of medical fitness

Question 6. Do you have specialized medical teams within the health care system to carry out assessment of medical fitness to drive when it comes to sleep apnoea or narcolepsy?

Question answered:

14 countries responded

The majority of countries neither have specialized medical teams within the health care system to carry out assessment of medical fitness to drive nor have on-road assessment when assessing fitness to drive when it comes to sleep apnoea or narcolepsy.

Details:

- 8 countries answer NO
- 6 countries answered YES and the following comments were provided:
 - In 1 of those countries doctors at Assessment Institutes carry out assessment of medical fitness to drive
 - Even if some countries answer YES, they give details which clearly show that they do not have any specialized teams
- 1 country answered both YES and NO

Question 7. Do you have on-road assessment when assessing fitness to drive for patients with sleep apnoea or narcolepsy?

Question answered:

14 countries responded

The most countries do not have on-road assessment.

Details:

- 10 countries answered NO
 - In 1 of those countries an on-road assessment can be performed anyway if the doctors need it
- 4 countries answered YES and the following comments were provided:
 - In 1 of those countries the police may require the applicant to submit an indicative health driving test to assess whether a driving license can be issued
 - In another of those countries an on-road assessment can be done to evaluate the alertness during longer drive

Question 7.a. If so, how is on-road assessment done (e.g. length, content, procedure)?

Question answered:

5 countries responded (of which 4 do not have an on-road assessment)

Only those 5 countries gave a more detailed description how the assessment is performed, for instance:

- An indicative health driving test takes 60 minutes. The driving test usually follows a more detailed route in and out of the city area, which operates at varying speeds, on different road types and with varying traffic intensities. The person concerned will be tested in the following elements: memory, orientation, space and direction sense and concentration
- The guidelines say that the on-road assessment should last longer than normal. There is no further guidance or regulations regarding on-road assessments. Physician can refer a patient

to on-road/practical driving assessment if he/she need further information to evaluate the alertness

- The type of on-road assessment is depending on the medical question and personal situation. Dual control cars, no fixed routes
- There is sometimes a mandatory person who sits near the driver
- The assessment will be adapted to what the county doctor wants evaluated

Question 8. Is there anything specific in the directives 2006/126/EC and 2009/113/EC, annex III on sleep apnoea and narcolepsy that you would like to see changed?

Question answered:

14 countries responded

Majority of countries do not see a need to introduce changes in Annex III in the directives concerning sleep apnoea and narcolepsy. Of the 6 countries that suggested a change made proposals focussing on a need to detail objective tests for measurement of excessive daytime sleepiness.

Details:

- 8 countries answered NO; some of those countries provided the following comments:
 - The architecture of regulations is well balanced, differentiated and coordinated between requirements by law and scientific recommendations
 - Regulation changed in 2011 with a very precise definition
 - This is assessed by medical specialists in health authorities
 - The mentioned directives are not specific concerning sleep apnoea and narcolepsy but Directive 2014/85 EU does so in relation to sleep apnoea
- 6 countries answered YES; the countries provided the following comments:
 - Review objective tests for sleep study measurements
 - Difference between central and peripheral causes
 - How and when to assess excessive daytime sleepiness objectively
 - Sleep apnoea is fine; for other hypersomnias, some general guidance as above would be helpful
 - We consider that the Directive has to define the minimums and specify them in technical guides
 - The construction of the relevant chapter in the Annex should be more precise concerning the conditions when the driving licence shall not be issued or renewed and when it may be issued or renewed if the condition has been effectively treated

3. GENERAL REMARKS AND CONCLUSIONS

General remarks

- The response rate on the questionnaire was low because only around a half of the countries which received the questionnaire sent their answers and some countries did not answer all questions in the questionnaire. The low response rate should be taken into account when reading the conclusions.
- The accuracy and quality of the answers varied and many answers were not clearly formulated and were not really well thought out.
- In many cases, it is not easy to fully understand how the processes around assessment of fitness to drive regarding sleep apnoea and narcolepsy are in fact constructed in each country.

Conclusions on the questionnaire sleep apnoea and narcolepsy

- The responses to the questionnaire showed that there are various administrative systems involved in the notification and investigation of drivers and applicants with sleep apnoea and narcolepsy. In the majority of countries, the system is based on medical certificates issued by authorised doctors, which have a crucial role. In a few countries, the doctors have a legal duty to report unfit drivers to the authority. In other countries, the doctors only need to inform the patients if they find them unfit to drive; they do not need to notify the authority. Unfortunately, the questionnaire responses did not deliver a clear answer as to whether this is an authority in each country or the doctors who finally decide if the licence has to be revoked or a new licence shall not be issued.
- The questions about narcolepsy and other central disorders of hypersomnolence were partially misunderstood and some countries answered here regarding sleep apnoea. The majority of countries do not have any specific regulations for these conditions, probably because the Directive 2014/85/EU on sleep apnoea does not contain them either. Only 3 countries suggest what regulation on narcolepsy should be included and two of them are in favour of giving a more decisive role to the doctors.
- Only a minority of the responding countries would introduce changes in Annex III in the Directives on sleep apnoea and narcolepsy. These countries generally wish for clearer criteria and recommended tests for the assessment of sleep apnoea as well as when the condition can be regarded as effectively treated.
- Based on the questionnaire responses, it is not easy to fully estimate if and how the answering countries have incorporated the Directive 2014/85/EU on sleep apnoea. The impression is however that the majority of the answering countries have done this.

Annex

Excel spreadsheet of responses.