CIECA Report Medical Fitness to Drive Diabetes

Report covering the answers to the questionnaire

about medical fitness to drive and diabetes

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CIECA Topical Group on Fitness to Drive

Sub group 2: Setting Standards for the Evaluation of Medical Fitness to Drive

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The International Commission for Driver Testing

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1. INTRODUCTION

This report summarizes the answers in the questionnaire regarding "Diabetes" which was sent to thirty-one countries within Europe. The questionnaire was answered by eighteen countries, although some of the countries did not answer all the questions. Some of those countries who did not answer all the questions, or where the answers needed clarification was contacted again. In some cases, but not all, new answers or clarification was received. Thirteen of the invited countries did not answer the questionnaire at all.

Part two of this report lists the questions sent to the countries and the answers received. Part three contains a conclusion concerning fitness to drive and diabetes, based on the answers.

Please note that the questionnaire only deals with issues of diabetes and group 2 licences, none of the questions are about group 1 licences.

2. ANSWER TO QUESTIONS IN THE QUESTIONNAIRE "DIABETES"

2.1. Question number 1

How is diabetes for group II drivers notified to the authority in your country?

In most of the countries that responded to the questionnaire it is the drivers themselves that notify the authority about their conditions. In most cases, this happens when the person applies for a driving licence for the first time and needs to attach a medical certificate to the application. In other countries, it is the professionals within the healthcare system or the police that notify the authority. However, it is required that they or the authority has information about the person's diabetes or gets the information under other circumstances. One country performs mandatory medical examination at certain time intervals. If the driver has diabetes, it will be detected during this mandatory medical examination. In some countries, the authorities will not be notified at all about a driver's diabetes.

Although many countries listed several examples of how the authority is notified, some countries listed just one or two. Therefore, the numbers of countries have not been specified as part of the results for this question.

2.2. Question number 2

Please describe the pathway and process from notifying diabetes for group 2 drivers to obtaining or retaining driving licence.

The responses to this question varied considerably in terms of detail. Below are the various areas that the answers addressed.

2.2.1. Medical assessment/check

Several countries require a medical examination or check-up in order to obtain or retain a driving licence for a group 2 licence. If the results from the examination are satisfactory, the authority takes a decision according to the legal requirement within the country. There is a difference between countries in terms of who is responsible for conducting the medical examination. In one country it is the general practitioners

(GP), in another it is the GP in cooperation with another specialist. In a third country the assessments are carried out at a driver assessment centre.

Some countries have a special form, a medical certificate, which a doctor needs to fill in and give to the driver. The driver is then required to submit the certificate to the authority. One country specifies that if the person has diabetes and is treated with insulin, glinides or sulphonylureas, a specialist in diabetes must fill in the form. One country requires a medical certification from the GP or endocrinologist that will be sent to the medical commission who makes a decision.

One country requires a new medical certificate every three years where a person has diabetes. If the driver does not fulfil the requirements or the regulations, the licence will be revoked.

In another country, it is the family physician who gives a medical certificate and if the applicant is diagnosed with diabetes, it is the regional health authority who makes the decision whether the patient may have a driving licence or not.

2.2.2. *Renewal every three or five years*

One country indicated that a group 2 driving licence must be renewed every five years. When the licence is renewed, a medical examination is required. In this country, diabetes is screened as standard and if there is a diagnosis or if the examiner has any doubt over the licence holder's condition, the person will be referred to a specialist who will submit a report regarding their fitness to drive. The medical doctor decides if the person is fit to drive or not according to the country's law. One country requires a new medical certificate every three years if the person has diabetes. If the driver does not fulfil the requirements or the regulations, the licence is revoked. In another country, a medical assessment is required once per year.

2.2.3. *Diabetes treated with medicines*

<u>Medicines with no risk of hypoglycaemia</u>

One country states that a driving licence can be approved for persons with diabetes who are not treated with a medicine that present a risk of hypoglycaemia.

<u>Medicines with risk of hypoglycaemia</u>

One country reported that if the person is treated with medicines that increases the risk of hypoglycaemia, a driving licence can only be approved on the basis of a favourable opinion from a specialist in internal medicine with special knowledge of diabetes (or the persons "own" doctor). The licence may then be valid up to three years and under certain specified conditions. One country uses a specially designed questionnaire to obtain the information needed to make a decision. This applies to first-time group 2 licence applicants who have insulin-treated diabetes. The applicant answers the first part of the questionnaire, the applicant's "own" doctor answers the second part and an independent specialist answers the third part. The licence is renewed every year and the full process applies every three year with a two-stage process in between (the questionnaires part two is not required).

One country specified that they require a personal health declaration and an examination performed by an internal specialist or a GP (depending on if the diabetes is treated with insulin or not). After obtaining this medical information, the driving licence authority makes the fitness to drive decision.

In one country, the driver who is treated insulin or other medication must meet the following criteria to obtain a group 2 driving licence:
- Present a specialist medical report proving that no severe hypoglycaemic events have occurred in the previous 12 months
- have good metabolic control of the disease
- have adequate control of the situation through regular monitoring of blood glucose, adequate therapeutic education and self-monitoring
- there are no complications associated with diabetes.

One country noted that medical fitness is influenced generally by anti-diabetic medication and the risk of hypoglycaemia. For group 2 licences severe hypoglycaemia may not have occurred within the past twelve months and if the diabetes is treated with insulin or medication with a high risk of hypoglycaemia the person should be educated, adhere to risk-minimizing strategies (based on self-monitoring and diet) and be shown to cooperate. This should be clearly documented in the medical record.

2.2.4. Police

In one country, the police are notified if the person does not meet the driving health criteria. In these cases, the police will impose a driving ban. If the situation proves and the person meets the criteria again, a physician provides a medical certificate to the authority and the person will regain their driving licence. However, this country did not describe how the police are notified or if the driving ban is limited in time and if so how long. In another country the doctor, by law, must report to the traffic police department if their patient has had severe hypoglycaemia or if their patient is unaware of hypoglycaemia. In these cases, medical fitness to drive should be re-assessed.

2.2.5. Adverse reactions

One country reported that driving competence is not assessed by the diagnosis, but by its serious adverse reactions. If the persons can maintain their status, under periodical specialist's controls, they can be considered fit for driving.

2.3. Question number 3

Do you have specialized medical teams within the healthcare system that carry out assessment of medical fitness to drive when it comes to diabetes for group II drivers?

Of the eighteen countries who answered the questionnaire, five responded that they have specialized medical teams within the healthcare system that conduct assessments for medical fitness to drive concerning diabetes and driving for group 2 licence holders. Thirteen countries indicated that they do not have such specialist medical teams. See Figure 1.

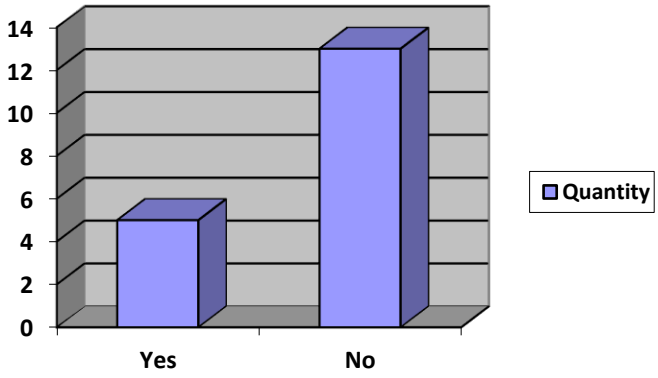

Figure 1 Involvement of specialist teams in assessing FTD for group 2 licences with diabetes.

The countries without medical specialist teams included the following comments with their answer:

- No, it is only the drivers own doctor within the healthcare system. However, the authority assesses the applicant's fitness to drive in cases regarding health.
- In a few university hospitals there are special clinics that make driving health assessments for challenging cases. Some private health organisations are also developing their own procedures. A physician can also refer a group 2 driver with diabetes to these health organisations if he/she (the physician, writer's remark) has difficulties in evaluating the situation.
- Not specifically for that purpose, however we do have a list of appropriate independent specialists who we refer drivers to as a part of the process.
- These problems are evaluated in the medical assessment.

Countries that answered they do have specialist teams included the following comments:

- Trained physicians approved by the administration (médecins agrées) who can seek a medical opinion from all specialized doctors if they need to. Occupational physician with regard to adaption to work.
- Medical-psychological assessment centre or consultant (qualification in traffic medicine).
- General physicians and specialists.
- The evaluation is carried out in private driver assessment centres, who always require specific information from the physician that treat the driver. On special occasions, we can consult with an expert from the health administration.
- We only use this team if the treating doctor is in doubt of anything.

2.4. Question number 4

Do you have on-road assessment in assessing fitness to drive when it comes to diabetes for group II drivers? If so – when and how is this done?

Twelve countries indicated that they do not have an on-road assessment for group 2 drivers with diabetes. Five countries do have an on-road assessment and one country answered ambiguously i.e. yes/no. See Figure 2.

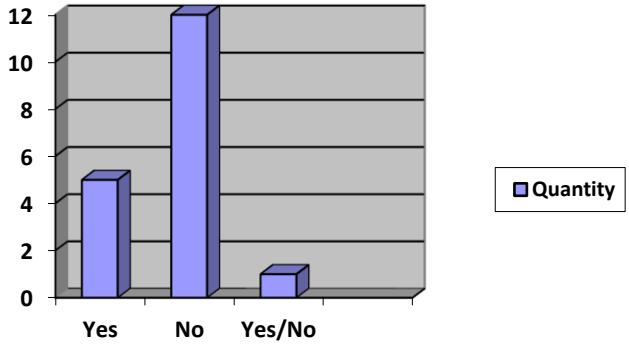

Figure 2 On-road assessment in assessing fitness to drive and diabetes.

The countries with on-road testing provided the following comments:

- Only occasionally and not regularly.
- The on-road assessment will only be performed in case of functional consequences of the diabetes. Hence this assessment is not for the diabetes itself, but for example because of locomotor issues (PNP and amputation) to determine adaptions for the car.
- In connection with the acquisition and renewal of driving licence, the police may require that the applicant submit to an indicative health-driving test to assess whether driving licence may be issued or (if necessary) issued on special terms. Such a driving test may also be required in order to determine to what extent a licence holder may continue to maintain the driving qualification.
- Only non-insulin dependent diabetes with visual disabilities.
- In general, the on-road assessment is not planned for drivers who suffer from diabetes. They are only performed in special cases where there are mobility problems or perceptual motor alterations.

Those who have answered no to the question give the following comments:

- Except if the médecins agrées requests it.
- Only if neurological deficits are present which require an on-road assessment.

2.5. Question number 5
Is it allowed to hold a group II licence with insulin dependent diabetes?

In all eighteen countries, group 2 drivers with diabetes who are treated with insulin are permitted to hold a group 2 driving licence (see Figure 3).

Two countries reported that the driving licence is valid for one year. Another country indicated that the licence is valid for three years.

Below are the additional comments that were provided by the respondents;

- Driving licence will be approved for a maximum of three years and under certain conditions.
- Emergency driving and category D for commercial passenger transport is never recommended for type 1 diabetes.
- This is provided for in the Directive.
- Licences are renewed annually.
- Licence may be approved under following criteria:
  A specialist medical report proving that no severe hypoglycaemic events have occurred in the previous 12 months.
  The person has good metabolic control of the disease.
  The person has adequate control of the situation through regular monitoring of blood glucose, adequate therapeutic education and self-monitoring.
  There are no complications associated with diabetes.
- Exceptionally and provided that the doctor who supervises the treatment of the driver issues a favourable report stating that the disease is well controlled and has sufficient training to control their disease. The licence has a duration of one year.
- Licence may be approved under following criteria:
  The diabetes is of type 2.
  The driver has full hypoglycaemic awareness or has never had an episode of hypoglycaemia and carries out self-monitoring of the blood-glucose level.
  No recurrent severe hypoglycaemic episode has occurred during the past 12 months.
- On the condition there has been no episode of severe hypoglycaemia in the last 12 months.
- If the person with diabetes is well aware of the risk of hypoglycaemia and are able to keep the condition under control, the person is fit to drive. Medical opinion of a specialist is needed if the person requires medication.

2.5.1. *Question number 5 a*

If so – what are the conditions under which one is allowed to hold a licence in group 2? Do you have specified criteria?

Almost every country answered this question in the same way: The conditions are the same as those stated in the 2009 Directive, for example medical examinations, the person's knowledge about the condition and regular monitoring of blood glucose. In addition to the criteria of the 2009 Directive, some countries mentioned other conditions and requirements for a group 2 driving licence holders, such as measuring of the blood glucose level while driving, use of a glucose meter with sufficient memory to store 3 months of reading and that the diabetes is type 2 .

Some countries responded that it is the requirements in the 2009 Directive that apply or they pointed to their own regulations without describing these any further.

Below is a selection of the responses submitted;

- There have been no episodes of hypoglycaemia (that needed help from another person) in the last twelve months. The person does not suffer from impaired awareness of hypoglycaemia.
  The person must check blood sugar for a minimum of two times per day and at times relevant to driving.
  The person must understand the risk of hypoglycaemia.
  No other complications that exclude driving.
  If there were some severe hypoglycaemia episodes while awake, driving licence for group 2 can be issued after a medical check-up three months after the episode

- Positive advice from endocrinologist.
  Stable situation.
  Adequate knowledge of the disease and risks.
  The person can recognise the symptoms.
  That the patient adheres to the therapy recommended by the doctor.
  Diabetes education and regular blood glucose test at least twice a day.
  A blood glucose test and additional blood glucose test at relevant times.
  Adequate knowledge of remediating actions.

- The person must not suffer from severe hypoglycaemia and/or impairment of the condition in either wake or sleep state.
  If a case of severe hypoglycaemia occurs, a medical driving ban should be issued for up to twelve months and driving with group 2 vehicles can only be resumed when the problem has been rectified.

- The person must have adequate knowledge of hypoglycaemia and the dangers posed as advised by the health check provider or the Traffic Medicine Commission.
  The person undergoes a medical examination at least once every three years.
  There are no complications associated with diabetes, which, according to the healthcare provider or the Traffic medicine Commission could affect the ability to drive.

- The person measures the blood glucose at least two times daily, before driving and every 2 or 3 hours when driving.
  The person has not had severe hypoglycaemia during last 12 months.
  The person recognises fully the symptoms related to low blood sugar.
  The person understands the risk that hypoglycaemia causes for driving.
  The risk related to high sugar levels is evaluated.
  No other diabetes related disease that essentially impairs driving capability,
  The person visits a doctor regularly because of diabetes and driving-capability is assessed every 1-3 years (no need to write a medical certificate though).

- All the following criteria must be met for the authority to licence the person with insulin-treated diabetes for 1 year:
  - Full awareness of hypoglycaemia.

- No episode of severe hypoglycaemia in the preceding 12 months.
- Practise blood glucose monitoring with the regularity defined in the box below.
- The person must use a glucose meter with sufficient memory to store 3 months of reading as detailed below.
- The person demonstrates an understanding of the risk of hypoglycaemia.
- There are no disqualifying complications of diabetes.

A. If on insulin, glinides or sulphonylureas:
- No episodes of hypoglycaemia requiring the assistance of another person has occurred in the preceding 12 months.
- The person has appropriate awareness of hypoglycaemia at appropriate glucose level.
- The person regularly monitors blood glucose at least twice daily and at time relevant to driving using glucose meter with a memory function to measure and record blood glucose levels.
- At the annual examination by a consultant endocrinologist, 3 months of blood glucose reading must be available.
- The person must demonstrate an understanding of the risk of hypoglycaemia.
- There are no other debarring complications of diabetes such as a visual field defect.

B. On medication other than A:
- Need not notify unless they developed relevant disabilities e.g. diabetic eye problems affecting visual acuity or visual fields, in which case not fit to drive or short period licence.
- Drivers are advised to monitor their blood glucose regularly and at times relevant to driving. They must be under regular medical review.

C. Diet-controlled:
- The person does not need not notify the authority unless they developed relevant disabilities e.g. diabetic eye problems affecting visual acuity or visual fields, or if insulin is required.

- Specialised endocrinologist advice.
  The person is aware of the illness.
  The person is feeling the hypoglycaemia arriving and able to react adequately.
  Immediate disposability of glucose.
  The person does regular auto measurement of his glycaemia or better continuous measurement by subcutaneous device.

- The person has not had severe hypoglycaemia in the past year.
  The person is aware of the risk of hypoglycaemia.
  The person has hypoglycaemias beware of hypoglycaemia and is able to deal with them adequately.
  The person performs self-monitoring at least twice a day and at times relevant for driving by means of a blood glucose test.
  The person does not have a serious diabetic complication.

- A report from a specialist on internal medicine is required for each assessment and a report from an ophthalmologist at least every five years.
  The maximum fitness period is 3 years.

- Each licence holder is subject to annual medical review, including supervision by independent specialist.
- Medical assessment to obtain or revalidate the driving licence may determine to maintain or retain the licence. Consideration may be given to the issuing/renewal of group 2 licences to drivers with diabetes mellitus. When treated with medication (oral antidiabetic) or insulin treatment, the following criteria should apply:
  - The person present a specialist medical report proving that no severe hypoglycaemic events have occurred in the previous 12 months.
  - The person has good metabolic control of the disease, through regular monitoring of blood glucose.
  - The person has adequate control of the situation and adequate therapeutic education and self-monitoring
  - There are no complications associated with diabetes.
- Exceptionally and provided that the doctor who performs the treatment of the driver issues a favourable report stating that the disease is well controlled and has a good training to control their disease. The licence has a duration of one year.
- The diabetes is of type 2.
  The person has full hypoglycaemic awareness or has never had an episode of hypoglycaemia.
  The person carries out self-monitoring of the blood glucose level.
  No recurrent severe hypoglycaemic episode may have occurred during the past 12 months.
  In some cases, persons with type 1 diabetes can obtain a group 2 licence. These are special cases and the driver has to apply for exceptions from the authority.
- The person must show proof of stable adjustment over 3 months.
- The candidate with diabetes is fit to drive if he is sufficiently aware of the risk of hypoglycaemia and is able to keep the condition under control. Medical opinion of a specialist is needed if the candidate is under medication. The candidate is fit to drive if:
  - no severe hypoglycaemia has occurred for at least 12 months before the examination,
  - the person is sufficiently aware of the initial symptoms of hypoglycaemia,
  - the person keeps the condition under control by measuring the blood sugar level at least twice a day and before driving,
  - the person is sufficiently aware of the risk of hypoglycaemia,
  - there is no other prohibitive condition related to diabetes
- No severe hypoglycaemia has occurred in the past twelve months.
  There is no hypoglycaemia unawareness.
  The person has education.
  The person show adherence to risk-minimizing strategies (based on self-monitoring etc.).
  The person shows proof of cooperation (frequent SMBG, CGM, i.e.).

2.5.2. *Question number 5 b*

When it comes to future risk of severe hypoglycaemia – what criteria do the authorities use or assessing physicians use to assess this?

Sixteen countries described how they assess the future risk of severe hypoglycaemia. One country did not answer the question and one country mentioned the Directive without further comment.

Below are the various areas that the answers have addressed.

2.5.2.1 Regular self-monitoring

In some countries one criteria in assessing the future risk of severe hypoglycaemia is that the person demonstrates a regular self-monitoring of blood glucose. One country specifies the criteria as the clinical assessment supported by blood glucose monitoring. Several countries specify the criteria contained in the Directive, among other things the requirement about measuring the blood-sugar level at least twice a day and before driving.

2.5.2.2 Insight and knowledge

Some countries specify criteria such as the person's insight and knowledge to assess the risk of future hypoglycaemia. The person must have an insight and knowledge of the disease and be loyal to the therapy. The person needs to understand the risk of hypoglycaemia and knows how to act when such an event occurs. One country indicated that the person is unfit to drive if the person demonstrates having no adequate control of the situation and is unaware of the risk of hypoglycaemia. Several countries specify the criteria contained in the Directive, among other things the requirement about the driver's full hypoglycaemic awareness and understanding of the risks of hypoglycaemia. One country reported that hypoglycaemia is a life-threatening condition that usually hits a patient quite quickly. Some, but not all patients are aware of hypoglycaemia and that eating or drinking something can help to avoid the episode. The risk of hypoglycaemia is often a problem at night during sleep. Incidentally, most people with diabetes diabetics understand how life-threatening hypoglycaemia is and try to avoid it.

2.5.2.3 Medical certification and examination

In case of treatment that causes a risk of hypoglycaemia, an opinion from a specialist in endocrinology/internal medicine or a doctor is required in some countries. In one country, the doctor should complete a special diabetes certificate. The following conditions must then be met, as per the criteria as set out in the 2009 Directive:

- There have been no cases of hypoglycaemia including hypoglycaemia during sleep over the past 12 months.
- The applicant can recognize and respond to warning symptoms for hypoglycaemia.
- In the medical examination, the applicant must demonstrate ability to control the disease by regular blood glucose measurement, at least twice a day and at times when driving.
- In the medical examination, the applicant must prove that he/she understands the risk associated with hypoglycaemia.
- There should be no other complications, such as visual impairment, neuropathy or

cognitive impairment, which may pose a risk to road safety in connection with diabetic disease.

Another country indicated that the people who conduct the medical examination decide whether or not a driving licence can be approved. This also depends on the driver's health status. Furthermore, the driver has to take and pass a medical examination more frequently than what is generally specified in the country's traffic law.

Two countries answer that the person must go through an examination by a specialist in internal medicine. In one of those countries, this is done every year.

2.5.2.4 Loss of consciousness

In one country the criteria for refusing a licence are loss of consciousness and the need of intervention from another person for resupplying the person with glucose. Another country specify that licences will not be authorized in cases of severe recurrent hypoglycaemia or in case of negative report from the driver's doctor.

2.5.2.5 Severe or recurrent severe hypoglycaemia

One country specifies that one criterion of assessing the risk of future hypoglycaemia is the driver's condition twelve months after a severe hypoglycaemia. Another country specifies that the person is unfit to drive if the person has recurrent severe hypoglycaemic episodes during waking hours. In these cases, a driving licence cannot be issued or renewed until three months after the most recent episode. In a third country the criterion is the number of severe hypoglycaemic episodes experienced in the preceding twelve months. Another country specifies that no severe hypoglycaemic episode may have occurred during the past twelve months. One answer indicated that critical criteria for assessing the future risk of hypoglycaemia are that no severe hypoglycaemia occurred in the past twelve months and that there is sufficient hypoglycaemic awareness.

2.5.2.6 Type of diabetes

In one country one criterion is the type of diabetes i.e. type 1 or type 2.

2.5.3. Question number 5 c

Is type of diabetes (type 1 or type 2) such a criterion?

Eleven countries reported that the type of diabetes is not a criterion in assessing future risk of severe hypoglycaemia. Five countries indicated that type of diabetes is a criterion and two countries did not answer the question. See figure 4.

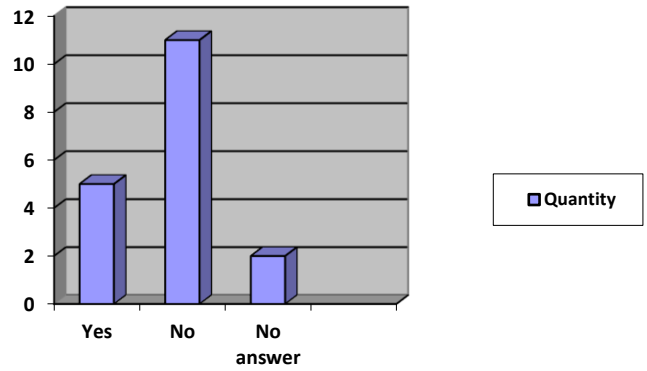

Figure 3 Type of diabetes is a criterion in assessing FTD.

The countries that include the type of diabetes as a criterion included the following comments:

- Professional driving licence cannot be recommended for category D1 and D or to persons who drive emergency vehicles if the applicant has type 1 diabetes due to the particular risks associated with this type of diabetes and the particular risks that is driving such vehicles.
- Because the treatment is different in diabetes 1 or 2. If insulin is used, the risk of hypoglycaemia is the highest and retains our whole attention. Sulfonamides in diabetes type 2 are also at risk of hypoglycaemia. The other medications of diabetes have no risk or a very low risk of hypoglycaemia.

The countries that do not use the type of diabetes as a criterion provided the following comments:

- The criterion is the treatment.
- The criterion is the treatment rather than the type. Some people with type 2 diabetes require insulin.
- It is not specified in the regulation.
- The health assessment guideline (the country's own guideline, writer's remark) do not differentiate diabetes types in assessing the fitness to drive and future risk of hypoglycaemia. It is important to assess the risk of hypoglycaemia but the type itself is not considered a criterion in the guidelines (but of course, insulin treatment, multiple daily injections and higher insulin amounts are more common in type 1).
- There is no difference between type 1 and type 2 diabetes by law or in a practice regarding hypoglycaemia and driving

The countries that *not* answered the question leave the following comments:

- As we have taken over the regulation as written in the Directive, the answer is not theoretically, for the moment. In practice, however, doctors can of course consider it.
- The law is stricter for diabetes type 1 and those of type 2 who are treated with insulin.

2.5.4. *Question number 5 d*

Do C-peptide has a place in this assessment?

Four countries reported that C-peptide features in the assessment of future risk of hypoglycaemia and twelve countries answer that C-peptide is not used in the assessment. Two countries did not answer the question at all. See Figure 5.

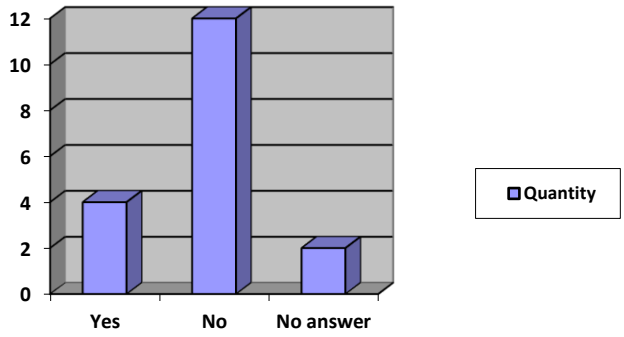

Figure 4 C-peptide as a criterion for assessing FTD.

One country that uses C-peptide measurement mentioned the value of HbA1c. Another country mentioned that the crucial element is the risk of severe hypoglycaemia and not the parameters during the treatment of the patient. In one country, the C-peptide is only assessed if it is a question of exception from the regulations (this country is included in the Yes responses in Figure 5). In one country, C-peptide is a normal test used by doctors.

Comments from those who answered no to the question is that this is not specified in the regulations, it is not performed routinely, or it might be a factor if the physician requires it. One country explained that they rely on the value of HbA1c which indicate the balance of blood sugar level (at fitness to drive assessment). The use of C-peptide is not obligatory and there are no recommendations for analysing C-peptide. Another country stated that C-peptide is a “medical nonsense”.

2.5.5. *Question number 5 e*

Does the use of an insulin pump/sensor/sensor augmented pump system affect the decision on allowing for a group 2 licence?

Twelve of the countries answered no to the question, three answered yes and three did not answer at all. See Figure 6.

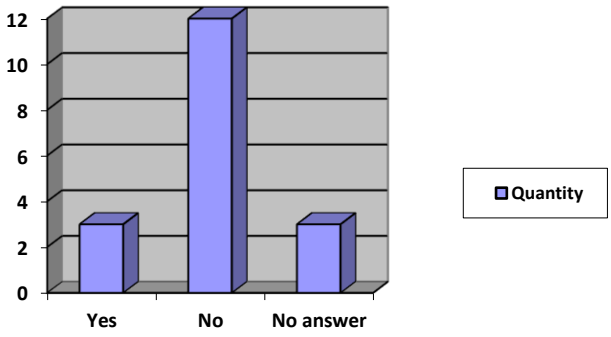

Figure 5 Use of insulin pump/sensor/sensor augmented pump.

The countries who answered no to the question provided the following comments as part of their responses. One country reported that this kind of device helps to conform to all the requirements to lower the risk. However, the drivers do not need to use this kind of device, and if they do it does not guarantee them a positive decision. Another country stated that even though the drivers are using an insulin pump or a sensor, they must also measure the blood glucose before and during the drive. A third country answered that it is not considered as a separate factor to be tested or evaluated in their jurisdiction.

In one country, this is under review.

One of the countries that did not respond to the question stated that this is not specified in the legislation.

One of the countries that answered yes to the question included the following comments: CGM technology (alone or in connection with pumps) significantly reduces the risk of hypoglycaemia. Not pumps alone, however. These devices are not required as a condition for driving licence

2.6. Question number 6

Do you generally allow sensor values instead of blood glucose values when it comes to measuring "two times daily and at times relevant to driving"?

Five countries answered yes to this question; they allow values from a sensor instead of values from blood glucose. Seven countries do not allow sensor values and six countries did not answer the question (see Figure 7).

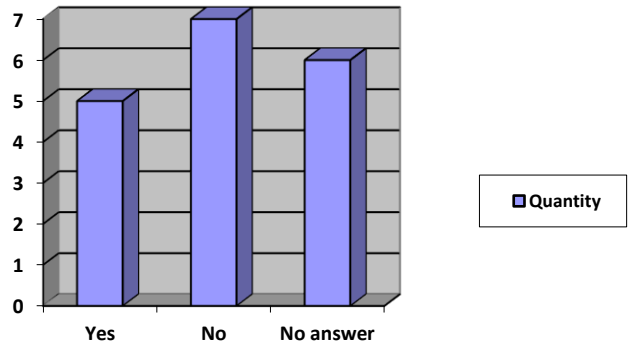

Figure 6 Do you allow sensor values instead of blood glucose values?

Two of the countries that allow sensor values added a comment to their answer. One country stated that the choice is left at the discretion of the deciding medical doctor. The other country reported that they generally allow sensor values instead of blood-glucose values, but if the person is unsure of the result of the sensor the person is further controlled by the self-monitoring blood glucose (SMBG).

Of the seven countries who answered no to the question, one country is considering alternative methods of glucose measurement for group 1 only, in consultation with the expert on their Medical Advisory Panel on diabetes. In another country, this is under discussion and in a third country this is under review. One country specified that only blood glucose monitoring is acceptable.

Six countries did not answer the question at all but did provide some comments. One country stated that this is not regulated, and the writer's opinion is that the doctors do not consider this. Furthermore, they are going to make a clinical guide to set the criteria. In other countries, the physician is the one who decides, or it is done by a case-by-case assessment. One country commented that this is not specified in the legislation and another country explained that this question could not be answered with a simple yes or no. The related regulations do not specify the blood glucose measurement technique which falls under the remit and competence of the competent doctor.

2.7. Question number 7

Is the writing in the annex substantial or specified enough to give equal results of medical fitness assessment in all European countries when it comes to diabetes for group II drivers?

The respondents from twelve countries believe that the wording in the Annex is specified enough but those from three countries disagreed with this view. Three countries did not answer the question (see Figure 8).

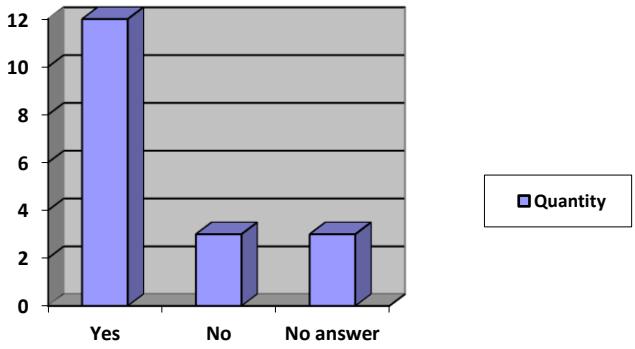

Figure 7 Is the Annex III specified enough when it comes to diabetes?

Most of the countries that answered the question think the writing in the Annex is specified enough to give consistent results of medical fitness assessments when it comes to diabetes in group 2 drivers. One country expressed that the chapter about diabetes was changed in 2010 and further amendments are not necessary. It would be desirable to focus on other issues. Another country answered that they might have interpreted the Directive quite loosely or alternative other member states have interpreted the Directive quite strict. The opinion in one country is that the Directive is clear when it comes to diabetes for group 2 drivers and one country write that the Directive is adequately specific and substantive for EU comparisons. One country suggested that in general the Annex is specified sufficiently, but local conditions may differ.

Those countries who answered no to the question provided the following comments. The Directive describes what to measure and to control, but it does not say how it should be done. Is it all right for a country to exclude a specific group completely, such as persons with type 1 diabetes or not? One country has undertaken a study to show variability among how the Directive is interpreted among different EU countries. It is not clear if this study is finished yet or if it is a work in progress. In one country, national guidance material has been critical to allow decision-making support to the physician.

2.8. Question number 8

Do you find anything special in the directives 2006/126/EC and 2009/113/EC, annex III on diabetes that you would like to see changed for group II drivers?

Respondents from eleven countries do not think that the Directive needs to be changed regarding the requirements for diabetes. Three countries would like to see a change and four countries did not answer the question (see Figure 9).

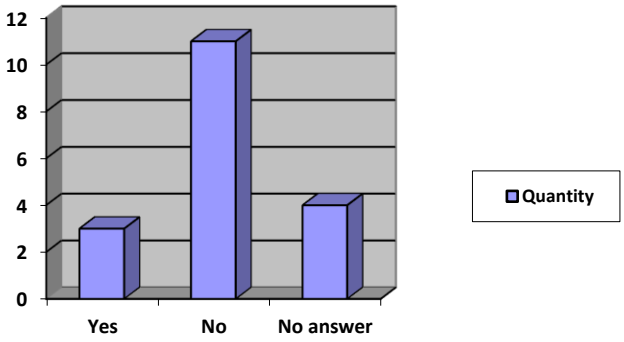

Figure 8 Does the Directive need changes regarding the requirement for diabetes?

One of the countries that answered no noted that it is important to leave some leeway for the physician when issuing their medical opinion. It would be dangerous to have a Directive with rigid limits. One country stated that they are quite happy with the status quo. They feel that there is no discrimination for diabetic drivers in this country in terms of the medical system or the law.

Some observations raised by those who would like a change include:

- Is CGM sufficient for glucose control or is blood glucose measurement necessary?

- How should we assess hypoglycaemia awareness?

- The limited time validation for group 2 should be five years instead of three years.

- The mandatory advice of an endocrinologist should be removed, it is often difficult for the patient to obtain. Many patients consult the general physician more and more often for their treatment. There are also great delays as appointments at an endocrinologist are difficult to obtain. A mandatory advice from an endocrinologist should only be requested if there are specific problems.

3. CONCLUSION

This report shows clearly that it was quite difficult to compile the answers in the questionnaire into a readable report. There are some things to consider before any final conclusion can be drawn. Some of the countries for example, just answered one or two questions in the questionnaire. A request for clarification was sent to some countries, but not all of these countries responded to the request. Some countries just refer to their own rules system without further explanation. In some cases, the question was not answered and the comment “this is not specified in the regulation” was provided. Other countries gave the same answer to several of the questions, which might indicate that the questions are unclear.

It is also important to keep in mind that the questionnaire was sent to thirty-one countries, of which thirteen countries did not respond to the questionnaire at all. Of those eighteen countries who did answer the questionnaire, some countries did not respond to all of the questions. Therefore, the response rate for each question was relatively low.

In several questions, the countries provided different levels of detail; some were very detailed and some submitted just a few words. It is likely that the countries sometimes handle things in a similar way, but it is not easy to conclude from the responses to the questionnaires. A prime example of this was question 5a related to the approval of a group 2 licence.

Nevertheless, responses provided for many of the questions are similar, which indicate that most of the countries interpreted the directive in a similar way in many areas. However, the responses for two of the questions serve to highlight differences between the countries. Answers to question *5 e* (if the use of an insulin pump or sensor affect the decision on allowing licence for group 2 driver's) shows that this is handled differently between the countries. Some countries say that this kind of device helps to lower the risk of hypoglycaemia, but the person needs to measure the blood sugar anyway. That is that the pump or sensor helps to lower the risk, but not alone. The requirement in the Directive says that the driver has to measure the blood sugar level at least twice a day and before driving. The issue is that if a person measuring the glucose level with a pump or sensor fulfils the Directive since these devices measure the glucose level in the interstitial fluid instead of the glucose level in the blood. Some countries answered 'yes' to question *6* (if they allow values from a pump or sensor instead of values from blood glucose when it comes to the requirement to measure the blood sugar level at least twice a day and before driving). It is worth noting that this question that received the lowest number of responses, seven countries did not answer the question at all. In this question, one country pointed out that according to the Directive it has to be the value of the blood sugar and one country wrote that the regulation does not specify the blood measurement technique (the author interpreted this answer as referring to the requirements of the Directive and not the national regulations). One country reported that they are considering approving these kinds of devices when it comes to group 1 drivers, but not for group 2. However, only one country stated that this is something that could be clarified in the Directive. The issue is whether the countries would have think differently if this was changed in the Directive. If the requirement was reformulated for example to *the driver has to measure the glucose level in blood or the interstitial fluid at least twice a day and before driving,* would the use of a pump or sensor then be more accepted within the countries when it comes to allowing licence for group 2 drivers? Alternatively, would the requirements within the countries remain that the person in these cases also needs to measure the glucose level in the blood?

Another issue that stands out is what role the doctor who conducts the medical examination has in the final decision whether or not a driving licence can be approved/revoked. In some countries it is the doctor who decides if a driving licence can be approved or not, in other it is the authority that makes the decision but with the medical certificate as the basis. There is also a difference in what competence the doctor who is writing the medical certificate should have. In some countries, the doctor has to be an endocrinologist and in others it is the family physician who writes the certificate. In one country an independent specialist should be involved and in one country the evaluation is carried out in private assessment centres. One country stated this as something that should be changed in the Directive. However, since the questionnaire does not include how the law and the driving licence process work in the different countries, it is difficult to draw any conclusions about these differences.

It is also worth noting that the coherence of the answers to question number *5 d* (about whether C-peptide has a place in the assessment of future risk of severe hypoglycaemia), where the majority replied that C-peptide has no meaning when assessing the future risk of

hypoglycaemia. One country pointed out the value of HbA1c as a parameter they rely on prior to C-peptide and one country described C-peptide as a 'medical nonsense'. In several countries the occurrence of severe hypoglycaemia appears to be a more important factor in the assessment, or the fact that the person performs regular monitoring of blood sugar and demonstrate insight and knowledge of the disease.

It can be concluded that the Directive overall seems to have been interpreted in a similar way among those countries who responded to this questionnaire regarding diabetes and licence for group 2 licence holders. The majority of the countries think that the Directive is specific enough and that there is no need to amend the Directive. However, there are some areas where a clarification in the Directive could facilitate the application of the rules for the member states.

Annex

Excel spreadsheet of responses.

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