Ministerie van Infrastructuur en Milieu

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VOLKSGEZONDHEID
WELZIJN EN SPORT
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SCANPLAZA

Bestuurskern
Dir.Wegen en Verkeersveiligheid
Afd. Verkeersveiligheid en Wegvervoer
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Datum 14 maart 2016
Betreft Adviesaanvraag rijgeschiktheid bij diabetes mellitus

Ons kenmerk
IENM/BSK-2016/50983

Geachte heer Van Gool,

Langs deze weg verzoek ik u om mij te adviseren over rijgeschiktheid bij Diabetes mellitus. Aanleiding van deze adviesaanvraag het voorstel van de Europese Commissie tot wijziging van de eisen met betrekking tot deze aandoening in bijlage III van EU richtlijn 2006/126/EG betreffende het rijbewijs (derde rijbewijsrichtlijn).

Het voorstel tot aanpassing van bijlage III is tot stand gekomen op basis van advisering van de Diabetes werkgroep die bijeen is gekomen op 23 september 2015. Na instemming van het Europees Parlement en de Europese Raad moet Nederland uiterlijk op 1 januari 2018 de gewijzigde eisen hebben geïmplementeerd. Lidstaten mogen wel strengere eisen stellen, maar geen lichtere.

Ik verzoek u om bij uw advies, als dit aan de orde is, een voorstel op te nemen tot wijziging van de bijlage van de Regeling eisen geschiktheid 2000 en hierbij rekening te houden met de uitvoerbaarheid door het CBR.

Ik hoop op een spoedige advisering. Zonder tegenbericht verwacht ik uw advies uiterlijk in het laatste kwartaal van 2016 te ontvangen, maar niet eerder dan dat het Europees Parlement en de Europese Raad hebben ingestemd met het voorstel. Voor vragen naar aanleiding van deze brief kunt u contact opnemen met de heer A.J. van der Sar.

DE MINISTER VAN INFRASTRUCTUUR EN MILIEU,
namens deze,
DE DIRECTEUR WEGEN EN VERKEERSVEILIGHEID,

Mevr. drs. M. Sonnema

Bijlagen:
- Verslag van de diabetes werkgroep, bijeenkomst 23 september 2015.
- Voorstel tot wijziging van richtlijn 2006/126/EG (concept).
- Bijlage bij het voorstel tot wijziging van richtlijn 2006/126/EG (concept).

Bestuurskern
Dir.Wegen en Verkeersveiligheid
Afd. Verkeersveiligheid en Wegvervoer

Datum
14 maart 2016

Ons kenmerk
IENM/BSK-2016/48892

Council of the
European Union

Brussels, 8 March 2016
(OR. en)

6937/16
ADD 1

TRANS 72

COVER NOTE

From:	European Commission
date of receipt:	7 March 2016
To:	General Secretariat of the Council
No. Cion doc.:	D043528/02 Annex
Subject:	ANNEX to the Commission Directive amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences

Delegations will find attached document D043528/02 Annex.

Encl.: D043528/02 Annex

EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) XXX draft

ANNEX 1

ANNEX

to the

Commission Directive

amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences

ANNEX

to the

Commission Directive

amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences

Annex III is amended as follows:

(1) Section 9 ("CARDIOVASCULAR DISEASES") is replaced by the following:

"CARDIOVASCULAR DISEASES

9. Cardiovascular conditions or diseases can lead to a sudden impairment of the cerebral functions that constitutes a danger to road safety. These conditions represent grounds for establishing temporary or permanent restrictions to driving.

9.1 For the following cardiovascular conditions, driving licences may be issued or renewed for applicants or drivers in the indicated groups, only after the condition has been effectively treated and subject to competent medical authorization and if appropriate, regular medical assessment:

(a) brady-arrhythmias (sinus node disease and conduction disturbances) and tachy-arrhythmias (supraventricular and ventricular arrhythmias) with history of syncope or syncopal episodes due to arrhythmic conditions (applies to group 1 and 2);

(b) brady-arrhythmias: sinus node disease and conduction disturbances with second degree atrioventricular (AV) block Mobitz II, third degree AV block or alternating bundle branch block (applies to group 2 only);

(c) tachy-arrhythmias (supraventricular and ventricular arrhythmias) with

- structural heart disease and sustained ventricular tachycardia (VT) (applies to group 1 and 2), or

- polymorphic nonsustained VT, sustained ventricular tachycardia or with an indication for a defibrillator (applies to group 2 only);

(d) symptomatic of angina (applies to group 1 and 2);

(e) permanent pacemaker implantation or replacement (applies to group 2 only);

(f) defibrillator implantation or replacement or appropriate or inappropriate defibrillator shock (applies to group 1 only);

(g) syncope (a transient loss of consciousness and postural tone, characterized by rapid onset, short duration, and spontaneous recovery, due to global cerebral hypoperfusion, of presumed reflex origin, of unknown cause, with no evidence of underlying heart disease)(applies to group 1 and 2);

(h) acute coronary syndrome (applies to group 1 and 2);

(i) stable angina if symptoms do not occur with mild exercise (applies to group 1 and 2);

(j) percutaneous coronary intervention (PCI) (applies to group 1 and 2);

(k) coronary artery bypass graft surgery (CABG) (applies to group 1 and 2);

(l) stroke/transient ischemic attack (TIA) (applies to group 1 and 2);

(m) significant carotid artery stenosis (applies to group 2 only);

(n) maximum aortic diameter exceeding 5,5 cm (applies to group 2 only);

(o) heart failure:

- New York Heart Association (NYHA) I, II, III (applies to group 1 only),

- NYHA I and II provided that the left ventricular ejection fraction is at least 35% (applies to group 2 only);

(p) heart transplantation (applies to group 1 and 2);

(q) cardiac assist device (applies to group 1 only);

(r) valvular heart surgery (applies to group 1 and 2);

(s) malignant hypertension (elevation in systolic blood pressure $\geq$180 mmHg or diastolic blood pressure $\geq$ 110 mmHg associated with impending or progressive organ damage) (applies to group 1 and 2);

(t) grade III blood pressure (diastolic blood pressure $\geq$110 mmHg and/or systolic blood pressure $\geq$180 mmHg) (applies to group 2 only);

(u) congenital heart disease (applies to group 1 and 2);

(v) hypertrophic cardiomyopathy if without syncope (applies to group 1 only);

(w) long QT syndrome with syncope, Torsade des Pointes or QTc > 500 ms (applies to group 1 only).

9.2 For the following cardiovascular conditions, driving licences shall not be issued or renewed for applicants or drivers in the indicated groups:

(a) implant of a defibrillator (applies to group 2 only);

(b) peripheral vascular disease - thoracic and abdominal aortic aneurysm when maximum aortic diameter is such that it predisposes to a significant risk of sudden rupture and hence a sudden disabling event (applies to group 1 and 2);

(c) heart failure:

- NYHA IV (applies to group 1 only),

- NYHA III and IV (applies to group 2 only);

(d) cardiac assist devices (applies to group 2 only);

(e) valvular heart disease with aortic regurgitation, aortic stenosis, mitral regurgitation or mitral stenosis if functional ability is estimated to be NYHA IV or if there have been syncopal episodes (applies to group 1 only);

(f) valvular heart disease in NYHA III or IV or with ejection fraction (EF) below 35%, mitral stenosis and severe pulmonary hypertension or with severe echocardiographic aortic stenosis or aortic stenosis causing syncope; except for completely asymptomatic severe aortic stenosis if the exercise tolerance test requirements are fulfilled (applies to group 2 only);

(g) structural and electrical cardiomyopathies - hypertrophic cardiomyopathy with history of syncope or when two or more of the following conditions present: left ventricle (LV) wall thickness > 3 cm, non-sustained ventricular tachycardia, a family history of sudden death (in a first degree relative), no increase of blood pressure with exercise (applies to group 2 only);

(h) long QT syndrome with syncope, Torsade des Pointes and QTc > 500 ms (applies to group 2 only);

(i) Brugada syndrome with syncope or aborted sudden cardiac death (applies to group 1 and 2).

Driving licences may be issued or renewed in exceptional cases, provided that it is duly justified by competent medical opinion and subject to regular medical assessment ensuring that the person is still capable of driving the vehicle safely taking into account the effects of the medical condition.

9.3 Other cardiomyopathies

The risk of sudden incapacitating events shall be evaluated in applicants or drivers with well described cardiomyopathies (e.g. arrhythmogenic right ventricular cardiomyopathy,

non-compaction cardiomyopathy, catecholaminergic polymorphic ventricular tachycardia and short QT syndrome) or with new cardiomyopathies that may be discovered. A careful specialist evaluation is required. The prognostic features of the particular cardiomyopathy shall be considered.

9.4 Member States may restrict the issue or renewal of driving licences for applicants or drivers with other cardiovascular diseases.";

(2) Point 10.2 of section 10 ("DIABETES MELLITUS") is replaced by the following:

"10.2 An applicant or driver with diabetes treated with medication which carries a risk of inducing hypoglycaemia shall demonstrate an understanding of the risk of hypoglycaemia and adequate control of the condition.

Driving licences shall not be issued to, or renewed for, applicants or drivers who have inadequate awareness of hypoglycaemia.

Driving licences shall not be issued to, or renewed for, applicants or drivers who have recurrent severe hypoglycaemia, unless supported by competent medical opinion and regular medical assessment. For recurrent severe hypoglycaemias during waking hours a licence shall not be issued or renewed until 3 months after the most recent episode.

Driving licences may be issued or renewed in exceptional cases, provided that it is duly justified by competent medical opinion and subject to regular medical assessment, ensuring that the person is still capable of driving the vehicle safely taking into account the effects of the medical condition."

Council of the
European Union

Brussels, 8 March 2016
(OR. en)

6937/16

TRANS 72

COVER NOTE

From:	European Commission
date of receipt:	7 March 2016
To:	General Secretariat of the Council
No. Cion doc.:	D043528/02
Subject:	COMMISSION DIRECTIVE (EU) .../... of XXX amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences (Text with EEA relevance)

Delegations will find attached document D043528/02.

Encl.: D043528/02

EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) XXX draft

COMMISSION DIRECTIVE (EU) .../…

of XXX

amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences

(Text with EEA relevance)

COMMISSION DIRECTIVE (EU) .../...

of XXX

amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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

Whereas:

(1) Scientific knowledge on medical conditions which affect fitness to drive has progressed since the adoption of Directive 2006/126/EC, in particular as regards the estimation of both the risks for road safety associated with the medical conditions and the effectiveness of treatment in averting those risks.

(2) The current text of Directive 2006/126/EC no longer reflects the latest knowledge on disorders that affect the heart and the blood vessels which either pose a current or a prospective risk of a significant, sudden and disabling event, or impair an individual from safely controlling their vehicle, or lead to both consequences.

(3) The Committee on driving licences has established a Working Group on Driving and Cardiovascular Diseases with the objective to assess the road safety risks associated with cardiovascular diseases from a current medical perspective and to formulate appropriate guidelines. The report[2] produced by the working group demonstrates why it is necessary to update the provisions on cardiovascular diseases in Annex III to Directive 2006/126/EC. It proposes to take into account the latest medical understanding and to clearly indicate for which conditions driving should be allowed and in which situations driving licences should not be issued or renewed. Furthermore, the report includes detailed information on how the updated provisions on cardiovascular diseases should be applied by the competent national authorities.

(4) The knowledge and methods for diagnosing and treating hypoglycaemia have advanced since the last update of the provisions on diabetes in Annex III to Directive 2006/126/EC in 2009. The Diabetes Working Group, established by the Committee on

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1 OJ L 403, 30.12.2006, p. 18.

2 New Standards for Driving and Cardiovascular Diseases, Report of the Expert Group on Driving and Cardiovascular Diseases, Brussels, October 2013.

driving licences, has concluded that those developments should be taken into account by updating those provisions, in particular concerning the relevance of hypoglycaemia occurring during sleep and duration of the driving ban following recurrent severe hypoglycaemia for group 1 drivers.

(5) To appropriately take into account individual specificities and to adapt properly to future developments in these medical fields, Member States should be provided with an option for the competent national medical authorities to allow driving in duly justified individual cases.

(6) Directive 2006/126/EC should therefore be amended accordingly.

(7) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents[3], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(8) The measures provided for in this Directive are in accordance with the opinion of the Committee on driving licences,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2006/126/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 1 January 2018 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

   They shall apply those provisions from 1 January 2018.

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

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

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

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[3] OJ C 369, 17.12.2011, p. 14.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR MOBILITY AND TRANSPORT

Directorate C - Innovative & sustainable mobility
C.4 - Road safety

Brussels,

Adopted minutes of the diabetes working group established by the Driving licence committee

Meeting of 23 September 2015 (09h30-16h30)

The driving licence committee meeting of 30 June 2015 decided to reconvene the diabetes working group to discuss the drafting of possible amendments to the diabetes provisions in Annex III of Directive 2006/126/EC on driving licences, in particular as regards hypoglycaemias during sleep for group 1 licences.

The Diabetes working group met on 23 September 2015 in Brussels at the premises of DG MOVE. The following Member States sent their medical experts to the meeting: Belgium, Germany, Finland, Ireland, Netherlands, Sweden, United Kingdom and Norway.

Concerns with the current provisions on diabetes in Annex III of Directive 2006/126/EC on driving licences

The current provisions on diabetes in Annex III were last updated in 2009 on the basis of the recommendations and the report of the diabetes working group that met in 2004. After the application of the diabetes provisions the Commission has been made aware by several Member States and citizens that the current provisions for group 1 drivers are too strict and that hypos occurring during sleep should not have the same weight in the assessment of fitness to drive as hypos occurring during waking hours. Furthermore, there were complaints that the driving ban of 12 months after a person had recurrent severe hypoglycaemia is far too strict because in most cases after proper treatment by a clinician a person could be deemed fit to drive much earlier.

Defining hypo awareness

The group agreed that it is very difficult to define hypoglycaemia awareness as it can fluctuate for a patient over very short periods of time and it also depends to some extent on how much previous experience someone has with hypos. The fact that a patient has recurrent severe hypos does not necessarily mean that he has hypo unawareness but it can be due to other factors, such as social constraints at that moment. The experts explained that the wording in the provisions should be changed from "impaired awareness" to "adequate" or "inadequate" awareness, as this reflects more properly the medical understanding.

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Relevance of hypoglycaemia during sleep

The definition of severe hypoglycaemia in the current diabetes provisions makes no distinction between hypoglycaemia occurring during sleep or while being awake. Some experts argued that the current provision would put persons living alone at an advantage as they have no partner that could pick up the signs during sleep and assist them, which would qualify the hypo episode as severe in accordance with point 10 of Annex III. Others argued that hypos can be more difficult to detect during hot weather and that many persons may not detect and react to the warning symptoms during sleep. Nevertheless, the group acknowledged that hypos during sleep should not be excluded but it should not automatically ban group 1 drivers from driving. Therefore, it was agreed that a driving ban shall only be imposed after recurrent severe hypoglycaemia during waking hours. Nonetheless, hypoglycaemia during sleep should still be taken into account during the regular medical assessment. The rules for group 2 drivers shall remain unchanged as they are having bigger risk exposure than group 1 drivers.

Period for driving ban

The current provisions on diabetes impose a driving ban of 12 months after recurrent severe hypoglycaemia. This time span is no longer medically justified as a skilled diabetes specialist may treat and restore a patient's health situation who suffered from recurrent severe hypoglycaemias within several weeks. The patient could be deemed fit to drive within a much shorter time span. The group agreed that after recurrent severe hypoglycaemia a 3 months driving ban after the most recent episode of severe hypoglycaemia would be a more appropriate duration. The patient would need to be undergoing regular medical assessments. On the basis of competent medical opinion, the 3 months driving ban could be extended to a longer period if necessary. The Commission recalled that the provisions in Annex III are minimum standards and that Member States could always introduce stricter requirements.

Treatment and assessment by a diabetes expert

The diabetes experts emphasised that it would be important that persons with recurrent severe hypoglycaemia are treated by a diabetes expert to ensure that they receive appropriate treatment.

The decision upon issuance/renewal of driving licences to a person with recurrent severe hypoglycaemia should also be based on the opinion of a diabetes expert. In order to ensure an objective opinion concerning the fitness to drive and to avoid any conflict between doctor and patient, the medical opinion should not come from the treating physician of the patient.

However, from a legal point of view the text can only refer to "competent medical opinion" as there are no European standards for what constitutes a "diabetes expert". Therefore, it should be left to each Member State to decide what can be considered as a "competent medical opinion", taking into account the specificities of national medical systems.

Medical and Scientific Progress

The group recognised that there are nowadays medical devices on the market that alarm the person before a possible hypoglycaemia attack. However, due to the high costs of the device it is not yet accessible to all diabetes persons with a risk of hypoglycaemia. Technical developments as well as progress in the drugs market will enable doctors to treat diabetes patients more efficiently. New technological and medical developments, which should improve the detection, treatment and prevention of hypoglycaemia, are expected to enter the market in the next two to three years. Consequently the new provisions should enable national authorities and doctors to take into account such developments and progress in the medical field. The group therefore agreed to introduce a flexibility clause. In addition, in order to take into account pharmaceutical developments, the diabetes experts concluded that it is necessary to widen the scope of point 10.3, by changing the wording in the brackets from "that is" to "such as", so as to include other forms of medication that can lead to hypoglycaemia.

Flexibility clause

The flexibility clause allows national authorities to issue/renew driving licences in duly justified exceptional cases to persons earlier than 3 months. This clause is not only allowing medical progress to be taken into account but enables national authorities to consider very specific individual circumstances which led to a person having recurrent severe hypoglycaemia. These individual exceptional cases could occur, for example, due to circumstances that are not expected to arise again, situations where the person cannot be held responsible for the hypoglycaemia episode, or when it is the result of inadequate health care or very serious acute illnesses.

Relevant scientific publication:

Giménez M, Lara M, Conget I. (2010) *Sustained efficacy of continuous subcutaneous insulin infusion in type 1 diabetes subjects with recurrent non-severe and severe hypoglycemia and Hypoglycemia unawareness: a pilot study.* Diabetes Technol http://www.ncbi.nlm.nih.gov/pubmed/20597825

Draft legislative text

The attached draft legislative text has been discussed during the working group meeting as well as by email exchange with the experts following the meeting. The group has endorsed the draft text. It was made clear that the third paragraph of point 10.2 stipulates the general conditions for recurrent severe hypoglycaemia, requiring that driving licences can only be issued or renewed subject to competent medical opinion and regular medical assessment. Furthermore, a requirement is added that licence should not be issued or renewed earlier than 3 months after the most recent hypoglycaemia episode in cases where hypoglycaemia occurs while being awake.

DIABETES MELLITUS

10. In the following paragraphs, a severe hypoglycaemia means that the assistance of another person is needed and a recurrent hypoglycaemia is defined as a second severe hypoglycaemia during a period of 12 months.

Group 1:

10.1. Driving licences may be issued to, or renewed for, applicants or drivers who have diabetes mellitus. When treated with medication, they should be subject to authorised medical opinion and regular medical review, appropriate to each case, but the interval should not exceed five years.

10.2.

A driver with diabetes treated with medication which carries a risk of inducing hypoglycaemia should demonstrate an understanding of the risk of hypoglycaemia and adequate control of the condition.

Driving licences shall not be issued to, or renewed for applicants or drivers who have inadequate awareness of hypoglycaemia.

Driving licences shall not be issued to, or renewed for, applicants or drivers who have recurrent severe hypoglycaemia, unless supported by competent medical opinion and regular medical assessment. For recurrent severe hypoglycaemias during waking hours a licence shall not be issued or renewed until 3 months after the most recent episode.

Driving licences may be issued or renewed in exceptional cases, provided that it is duly justified by competent medical opinion and subject to regular medical assessment ensuring that the person is still capable of driving the vehicle safely taking into account the effects of the medical condition.

Group 2:

10.3. Consideration may be given to the issuing or renewal of group 2 licences to drivers with diabetes mellitus. When treated with medication which carries a risk of inducing hypoglycaemia (such as, insulin, and some tablets), the following criteria should apply:

— no severe hypoglycaemic events have occurred in the previous 12 months,

— the driver has full hypoglycaemic awareness,

— the driver must show adequate control of the condition by regular blood glucose monitoring, at least twice daily and at times relevant to driving,

— the driver must demonstrate an understanding of the risks of hypoglycaemia,

— there are no other debarring complications of diabetes.

Moreover, in these cases, such licences should be issued or renewed subject to the opinion of a competent medical authority and to regular medical review, undertaken at intervals of not more than three years.