

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2016/1106

of 7 July 2016

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 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.

⁽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.

⁽³⁾ OJ C 369, 17.12.2011, p. 14.

- (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*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 7 July 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex III to Directive 2006/126/EC 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 authorisation 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, characterised 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 ≥ 180 mmHg or diastolic blood pressure ≥ 110 mmHg associated with impending or progressive organ damage) (applies to group 1 and 2);
- (t) grade III blood pressure (diastolic blood pressure ≥ 110 mmHg and/or systolic blood pressure ≥ 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.'
