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| Subject:         | ANNEX to the Commission Directive amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences |

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Delegations will find attached document D043528/02 Annex.

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ANNEX 1

**ANNEX**

**to the**

**Commission Directive**

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

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**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 syncope 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."