

EXPLANATORY MEMORANDUM TO
THE MOTOR VEHICLES (DRIVING LICENCES) (AMENDMENT)
REGULATIONS 2017

2017 No. 1208

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department for Transport and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 These Regulations make changes to medical standards in respect of drivers of Group 1 vehicles (mainly cars and motorcycles) who have diabetes mellitus. Amendments are made to regulation 72(4) and (5) of the Motor Vehicles (Driving Licences) Regulations 1999 (“the 1999 Regulations”) in order to implement paragraph (2) of the Annex of Commission Directive 2016/1106/EU on driving licences (“the 2016 Directive”). In addition, this instrument amends regulation 72(6) of the 1999 Regulations so that appropriate monitoring of glucose levels is sufficient to satisfy the prescribed condition.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Other matters of interest to the House of Commons

- 3.2 As this instrument is subject to negative resolution procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

- 4.1 These Regulations amend regulation 72(4)(a) and (5)(a) of the 1999 Regulations in order to implement paragraph (2) of the Annex of the 2016 Directive, which replaces point 10.2 of section 10 of Annex III (“Minimum standards of physical and mental fitness for driving a power-driven vehicle”) of Directive 2006/126/EC. The changes brought about by paragraph (2) of the Annex of the 2016 Directive are aimed at relaxing the rules which apply to Group 1 drivers with diabetes mellitus if their condition is adequately controlled and they do not endanger road safety.
- 4.2 The new point 10.2 provisions are already largely implemented by regulation 72(4) and (5) of the 1999 Regulations. The significant change concerns the standards that apply to Group 1 drivers with diabetes mellitus who have recurrent, severe hypoglycaemia. Recurrent hypoglycaemia is interpreted as a person who has 2 or more episodes of severe hypoglycaemia during a period of 12 months. Severe hypoglycaemia is where the assistance of another person is needed. The revised point 10.2 provisions allow persons who have 2 or more episodes of severe hypoglycaemia while awake, to be issued with a driving licence 3 months after the most recent episode, subject to competent medical opinion and regular medical assessment. This

is now implemented by the changes made by regulation 2(2)(a) and (b) of this instrument.

- 4.3 Regulation 2(2)(c) of this instrument amends regulation 72(6)(b) of the 1999 Regulations so that a Group 1 driving licence applicant under regulation 72(5) is required to undertake appropriate monitoring to assess glucose levels. This may include blood glucose monitoring but is not limited to that type of monitoring.
- 4.4 The current standards that apply to drivers with medical conditions are implemented by way of a combination of legislation and administrative guidance. The Secretary of State has a broad discretion to refuse a licence for any relevant disability which is likely to make the driving of a vehicle a source of danger to the public. Regulation 72(6) (d) of the 1999 Regulations means the Secretary of State must be satisfied that issuing a Group 1 licence to a driver who falls within regulation 72(5) is not likely to be a source of danger to the public and if not so satisfied the licence can be refused.

5. Extent and Territorial Application

- 5.1 The extent of this instrument is Great Britain.
- 5.2 The territorial application of this instrument is Great Britain. Northern Ireland will legislate separately to transpose the 2016 directive.

6. European Convention on Human Rights

- 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

7. Policy background

What is being done and why

- 7.1 Diabetes mellitus is a lifelong condition that causes a person's glucose level to become too high. It can cause long-term health problems particularly for eyesight, e.g. glaucoma, cataract and retinopathy. As of November 2016 there were 3.6 million people diagnosed with diabetes in the UK. The medication that diabetics take can cause their glucose levels to drop resulting in hypoglycaemia. Hypoglycaemia can give rise to various symptoms including dizziness, hunger, sweating and possible loss of consciousness.
- 7.2 Regulation 72(5) and (6) of the 1999 Regulations prescribe the conditions for the purposes of granting a Group 1 licence to a diabetic driver who is treated with insulin. The 1999 Regulations do not prescribe the conditions that apply to the grant of a Group 1 licence for diabetic drivers treated with medication, other than insulin. This category of driver will continue to be subject to similar conditions as those on insulin but this is set out in guidance. Greater flexibility is needed to determine licence periods for non-insulin diabetic drivers and therefore this is better dealt with in guidance. Treatment with insulin carries a higher risk of hypoglycaemia than other medication and so the grant of Group 1 licences to drivers on insulin is more restricted.
- 7.3 Currently under the 1999 Regulations, an individual treated with insulin may be issued with a Group 1 licence if they-
- have adequate awareness of hypoglycaemia,

- had no more than 1 episode of severe hypoglycaemia in the preceding 12 months,
 - can demonstrate an understanding of the risks of hypoglycaemia and adequate control of the condition,
 - undertake appropriate blood glucose monitoring,
 - are not regarded as a likely risk to the public while driving and are under regular medical review.
- 7.4 The current regulations have the effect of barring drivers of Group 1 vehicles from driving until the first severe hypoglycaemic episode drops out of a rolling 12 month period. This fails to recognise the particular circumstances of people who have hypoglycaemic episodes while asleep. A person who is awake has the opportunity to recognise and act upon any warning signs and prevent an attack, whereas a person who is asleep does not. In addition, methods for diagnosing and treating hypoglycaemia have advanced since the original European Directive was agreed.
- 7.5 The Secretary of State’s Honorary Medical Advisory Panel on Diabetes (“the panel”) is an advisory panel that works with the Driver and Vehicle Licensing Agency (DVLA) to provide expert advice with the aim of maintaining and improving road safety. The panel believes that treating severe hypoglycaemic episodes while asleep in the same way as episodes that occur while awake is unfair and unnecessary. Since 2011 the European Commission has been approached by several Member States including the UK with the view that the current provisions for Group 1 Drivers are too strict in this respect. The UK Government therefore supported a change to EU legislation to remove severe hypoglycaemic episodes occurring while asleep from consideration of whether there had been more than one episode in the preceding 12 months.
- 7.6 In addition and based on the panel’s recommendation, the UK Government supported a relaxation of the current rules so that diabetic drivers with recurrent severe hypoglycaemia (while awake) may be issued with a driving licence 3 months after the last episode of hypoglycaemia, as long as the other conditions mentioned above in paragraph 7.3 are met.
- 7.7 There have been technological advances in methods of monitoring glucose levels in the body. In addition to the “finger prick” test used to monitor blood glucose levels, there is now equipment that measures the glucose levels in interstitial fluid (a bodily fluid). These Regulations do not prescribe any particular method of monitoring, but remove the specific reference to “blood glucose monitoring” so that any new method of monitoring glucose that are suitably assessed by medical experts and endorsed as fit for purpose can be used instead of the “finger prick” test.

Consolidation

- 7.8 There are no plans to consolidate the legislation amended by these Regulations.

8. Consultation outcome

- 8.1 The department has been engaging with key stakeholders on the changes contained in this instrument over a lengthy period of time.
- 8.2 The two most prominent stakeholders for the DVLA are the Secretary of State’s Honorary Medical Advisory Panel (the panel) and Diabetes UK (DUK). The panel includes consultant diabetologists who are considered to be notable experts in the

field and it meets with representatives of the Driver and Vehicle Licensing Agency (DVLA) in March and October each year. The panel has considered these matters from its meeting of March 2011 onwards and has consistently advocated changes to legislation prior to presentation to the European Commission and since.

- 8.3 DUK are fully in support of the changes and place particular value on the need to distinguish between hypoglycaemias suffered while awake and while asleep. They wrote to the Minister following the adoption of the Directive asking for the legislation to be amended as soon as possible. They also strongly advocated for a more flexible approach to blood glucose monitoring and wrote to the Minister on 12 July 2017 requesting a meeting to put forward the case for a change to legislation. Although the meeting did not take place, they subsequently met with DVLA officials.
- 8.4 In addition, DVLA wrote in April 2017 to the Independent Diabetes Trust (IDT), the Association of British Clinical Diabetologists (ABCD) and the Diabetes Wellness Foundation, as we had not previously engaged with these organisations to the same extent. The Diabetes Wellness Foundation did not reply, but the IDT and the ABCD both supported the changes. The same letter was also sent to DUK and was discussed at the October 2017 panel meeting. Both organisations reaffirmed their support.
- 8.5 Concerning glucose monitoring, a number of interested parties have written to DVLA or to the Minister. They are Ascensia Diabetes Care Ltd, Abbott Diabetes Care Ltd and the Association of British Healthcare Industries. Ascensia manufactures the equipment used to conduct blood tests and they expressed some concern that the blood test would be superseded by equipment that measures the glucose in interstitial fluid. However, this SI does not endorse any particular equipment but gives discretion to the Secretary of State to determine which methods are suitable. Any future decisions on this will be informed by consultation with the panel. All the other stakeholders mentioned earlier in this paragraph supported the change. DVLA has also received an enquiry from NHS England, as a device designed to monitor interstitial fluid became available on the NHS on 1 November.
- 8.6 This instrument applies to Great Britain, and therefore Scottish Executive and Welsh Government colleagues have been informed about the substance of these changes.

9. Guidance

- 9.1 Comprehensive guidance for medical professionals on physical fitness to drive, including with regard to diabetes mellitus (i.e. the DVLA guidance titled ‘Assessing Fitness to Drive – a guide for medical professionals’) is published on the gov.uk website. The guidance is updated to address the changes made by these Regulations in relation to diabetic drivers. This updated guidance will be available on this website by 1 January 2018.

10. Impact

- 10.1 The impact on business, charities or voluntary bodies, if any, is not significant.
- 10.2 There is no impact on the public sector.
- 10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

- 11.1 The legislation does not apply to activities that are undertaken by small businesses.

12. Monitoring & review

12.1 A post implementation review will be conducted by 1 January 2022.

13. Contact

13.1 Dave Warren at the Driver and Vehicle Licensing Agency tel. 01792 83489 or email: dave.warren@dvla.gsi.gov.uk can answer any queries regarding the instrument.