EXPLANATORY MEMORANDUM TO

THE MOTOR VEHICLES (DRIVING LICENCES) (AMENDMENT) REGULATIONS 2011

2011 No. 2516

1. This Explanatory Memorandum has been prepared by the Department of Transport and is laid before Parliament by Command of Her Majesty.

This Memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 These Regulations amend the Motor Vehicles (Driving Licences) Regulations 1999 (S.I. 1999/2864) ("the 1999 Regulations").

2.2 They implement Commission Directives 2009/112/EC and 2009/113/EC of 25 August 2009 ("the 2009 Medical Directives"), which amend respectively Directive 91/439/EEC of the European Parliament and of the Council on driving licences ("the 2nd driving licence directive") and Directive 2006/126 EC of the European Parliament and of the Council on driving licences ("the 3rd driving licence directive").

2.3 The 2009 Medical Directives amend the minimum medical standards required for driving licensing, in respect of three medical conditions – being eyesight, epilepsy and diabetes mellitus ("diabetes").

2.4 The Motor Vehicles (Driving Licences) (Amendment) Regulations 2011 ("the 2011 Regulations") implement changes to driving licence medical standards in respect of diabetes.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 It is anticipated that further Regulations will be introduced to implement changes to medical standards for eyesight and epilepsy in 2012.

3.2 The changes introduced by the 2009 Medical Directives clarified and in some cases relaxed existing EU minimum driver licensing medical standards for diabetes, epilepsy and eyesight. The current UK standards, applied by way of a combination of legislation and administrative guidance, are in line with, or above, the minimum standards changed by these Directives (subject to some changes made to the administrative guidance), particularly since the Road Traffic Act 1988("the 1988 Act") gives the Secretary of State 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. Thus, there was no requirement for UK to adopt further laws by the implementation deadline of September 2009 and the UK therefore notified the European Commission of transposition in September 2010, based on its existing legislation and updated administrative guidance.

3.3 The 2011 Regulations implement the 2009 Medical Directives, by either: a) providing additional legal certainty, in giving legislative effect to GB standards previously applied by administrative guidance;

b) implementing options to relax existing medical standards contained in the 1999 Regulations for Group 2 (bus and lorry) licences.

3.4 In considering whether GB should take up the option to make substantive changes to relax its existing medical standards, the Secretary of State has asked for the views of the relevant expert medical panels and has carried out a public consultation. A number of issues are still being considered in relation to eyesight and epilepsy. Since all substantive issues in relation to diabetes have been resolved and a number of drivers with insulin treated diabetes are waiting to apply for Group 2 licences pursuant to the new relaxed EU standards, the minister has told Parliament that this aspect will be brought forward at the earliest possible date. For this reason, the options for change afforded by the 2009 Medical Directives will be implemented by way of two sets of Regulations rather than one.

4. Legislative Background

4.1 UK rules on driver licensing and driving tests currently operate within the framework of the 2nd Driving Licence Directive, adopted in 1991. This provides for mutual recognition of driving licences between Member States of the European Union and the European Economic Area, and harmonisation of the licensing categories and driving test standards.

4.2 The 3rd driving licence directive was adopted on the 20 December 2006. Its provisions are, for the most part, required to be transposed into national law by 19 January 2011 and to be implemented by 19 January 2013.

4.3 The 2009 Medical Directives amend aspects of the harmonised minimum medical standards for driving licensing, as contained in Annex III of the 2nd and 3rd Driving Licence directives. This Annex is identical in both Directives and the changes effected to it by the 2009 Medical directives are also the same for both Directives.

4.4 The Medical Directives were made under the EU comitology procedures (in particular under Article 5a(1) to (4) and article 7 of decision 1999/468/EC) and have therefore not been reviewed by the EU Scrutiny Committee.

4.5 In GB, the 2nd Driving Licence Directive is transposed by the 1988 Act and the 1999 Regulations made under it. The 1988 Act, the Road Safety Act 2006 and the 1999 Regulations are currently in the process of being amended to transpose the 3rd Driving Licence Directive and Regulations should be laid shortly.

4.6 The 1998 Act enables the Secretary of State to prescribe "a relevant disability" under section 92(2) of that Act. Under section 92(3) of the 1988 Act, if an applicant for a driving licence suffers from a relevant disability, the Secretary of State, must, subject to the subsequent provisions of section 92, refuse to grant a licence.

4.7 Section 92(4)(b) of the 1988 Act enables the Secretary of State to prescribe conditions in respect of a relevant disability prescribed for the purposes of that paragraph,

with a view to granting a licence to a person in whose case that disability is appropriately controlled..

4.8 The 2011 Regulations make changes to the circumstances in which diabetes is a prescribed disability and to the prescribed conditions under which a licence can be granted to a person with diabetes.

5. Territorial Extent and Application

5.1 This instrument applies to Great Britain. Northern Ireland will legislate separately to transpose the 2009 Medical Directives within that jurisdiction.

6. European Convention on Human Rights

6.1 Mike Penning, Minister for Transport, has made the following statement regarding Human Rights:

6.2 As these Regulations are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

Amendments to the Motor Vehicles (Driving Licence) Regulations 1999

Disabilities prescribed in respect of Group 1 licences

7.1 Diabetes requiring treatment with medication which carries a risk of inducing hypoglycaemia is a prescribed disability for Group 1 licensing, where the applicant has

- experienced two or more episodes of severe hypoglycaemia in the previous one year period; or
- has impaired awareness of hypoglycaemia.

7.2 These Regulations also prescribe conditions for the purposes of granting a Group 1 licence where diabetes treated by insulin is controlled. They do not prescribe conditions for the purposes of granting a licence to a person who has diabetes treated with medication which carries a risk of inducing hypoglycaemia, other than insulin. This category of person will continue to be subject to similar conditions as those on insulin, but these will be set out in guidance rather than legislation.

7.3 The effect of prescribing conditions for one class of person in legislation is that this class then cannot be granted a licence for longer than three years pursuant to section 99(1)(b) of the 1988 Act. In respect of the class for whom conditions are set down in guidance, the Secretary of State can still determine not to grant a licence for longer than 3 years, if it appears that the person is suffering from a prospective disability, but if the determination is that this is not the case, a full period licence until the age of 70 can be granted. Since treatment with insulin carries a higher risk of hypoglycaemia than treatment with other medication, greater flexibility is needed to determine licence periods in the latter case.

7.4 The 1999 Regulations do not currently prescribe circumstances where diabetes is a prescribed disability for Group 1 licensing and the 2011 Regulations therefore change the legislative position. However, this should make little difference in practice. There is already detailed administrative guidance for diabetes and Group 1 driving. An application for a Group 1 licence can currently be refused where the driving of a vehicle by the applicant is considered likely to be a source of danger to the public. Current administrative criteria for granting a Group 1 licence are very similar to the new prescribed conditions for insulin treated diabetes in the 2011 Regulations. Moreover, current administrative practice is to limit the period of licences for insulin treated diabetics as described in the previous paragraph.

7.5 The medical standards have been embodied in legislation, rather than administrative guidance alone, in order to give effect to the clearer standards now required by EU law. This gives greater legal transparency and certainty, but does not create any additional burden.

Disabilities prescribed in respect of Group 2 licences

7.6 Currently, the 1999 Regulations make diabetes requiring insulin treatment a prescribed disability for Group 2 purposes, except in the case of certain licence holders with "grandfather rights" who had the right to drive such vehicles on or before 1st April 1991.

7.7 The 1999 Regulations currently prescribe certain conditions under section 92(4)(b) of the 1988 Act for diabetes requiring insulin treatment, in the case of a person applying to drive C1, C1 +E, or C1 + E (8.25 tonnes) sub categories of Group 2.

7.8 Current administrative guidance requires applicants with diabetes managed by medication other than insulin, which carries the risk of inducing hypoglycaemia, to satisfy similar conditions to be granted a Group 2 licence. Those with "grandfather rights", as described in regulation 73(6) of the 1999 Regulations, prior to amendment, are also administratively made subject to these conditions and granted a licence for a period of not more than one year, on the basis that they suffer from a prospective disability.

7.9 The 2011 Regulations open up all categories of Group 2 licensing, for applicants with diabetes requiring treatment with medication which carries a risk of inducing hypoglycaemia (which includes insulin), subject to meeting conditions prescribed under section 92(4)(b) of the 1988 Act.

7.10 The conditions prescribed in the 2011 Regulations for all Group 2 licensing, are similar to those which were previously applied in the 1999 Regulations to the C1 sub categories. However, the conditions have been clarified to fully reflect the standards in the 2009 Medical Directives.

7.11 The grandfather right described in paragraph 7.8 above is removed because, for practical purposes it now becomes redundant. It previously conferred an entitlement to be considered for all categories of Group 2 licensing, (as opposed to C1 sub categories only, as was the case for other insulin treated diabetics). However, now that all Group 2 licence categories have been opened up to any applicant with insulin treated diabetes, who meets the prescribed conditions, it is no longer necessary. The removal of the

"grandfather right" does, however, have a legal effect in that the persons in the affected class are now treated as having a relevant controlled disability, rather than a prospective disability. This has the further consequence that the Secretary of State is now obliged to limit the duration of their licences to no more than 3 years, whereas there was previously a discretion to grant a longer licence. In fact, since the longstanding practice has been to grant such persons with grandfather rights a licence limited to one year only, in line with the advice of the Secretary of State's expert panel, this legal change simply reflects the current position in a more transparent way.

7.12 The EU requirement is for Group 2 drivers treated with medication carrying a risk of inducing hypoglycaemia, to have a minimum three yearly review by an expert. The mechanism used to achieve this in the 2011 Regulations, in cases where the affected licence holders meet the other mandatory EU conditions, is to prescribe such a disability for the purposes of section 92(4)(b) of the 1988 Act. In such cases, only one to three year licences can be granted, as explained in paragraph 7.3 above and a fresh medical review would be needed before a new licence could be granted. In one respect, DVLA proposes to apply a higher standard than the EU minimum. In the case of insulin treated Group 2 drivers, the advice of the Secretary of State medical panel is to conduct one yearly, as opposed to three yearly medical reviews. This advice has been accepted, as explained in DVLA's consultation. It will be actioned by limiting the licences granted to this class of driver to one year (by way of administrative decision, rather than by a provision in legislation).

7.13 Diabetes is the most common medical condition taken into consideration for driving licence purposes. It is thought that immediately around 3,000 Group 2 drivers will benefit from this change, either because they can apply to upgrade a C1 licence to a full Group 2 licence, or choose to apply for a Group 2 licence for the first time. There has been a medium level of public interest in the proposal from those with the condition, lobby groups and road safety organisations.

8. Consultation outcome

8.1 A consultation was issued on 3rd February 2011relating to the proposed changes in relation to diabetes, eyesight and epilepsy. This ended on 28th April 2011. Invitations to respond to the consultation were sent to 309 consultees, these included Motoring Organisations, Local Authorities, Police Organisations, Members of Parliament, Medical Charities and various other interested stakeholders. The consultation document was also published on the DfT and DVLA websites. In addition, the Driver and Vehicle Agency in Northern Ireland invited 54 consultees to respond and published the consultation document on their website. The Driver Standards Agency also notified 27,418 individual contacts electronically.

8.2 A total of 132 organisations and individuals commented on the proposals. These included a cross section of interested parties including individuals, Advanced Driving Instructors, General Practitioners, Local Government, Optical Organisations, Road Safety Organisations, Medical Charities and organisations who represent individuals with an interest in the medical fields of vision, diabetes or epilepsy.

8.3 Of the 132 responses to the consultation received, 35 related specifically to the diabetes proposals. Of these, 30 agreed with the proposals. Three disagreed because they considered further relaxation was appropriate; two responses were unclear.

8.4 59 responses commented on more than one condition; nine made comments on the Diabetes proposals, with eight supporting the recommendations. One respondee made a link to driving emergency vehicles, which is outside the scope of this consultation.

8.5 Responses were generally in favour of the proposed standards, particularly around individual assessment and allowing insulin treated diabetics to be considered for a Group 2 vehicle licence.

9. Guidance

9.1 Guidance will be available on the DVLA website and in notes accompanying application forms to educate the public as to the new standards. A press release will also be issued. Consultees who responded are being kept informed of the procedures as they are developed.

10. Impact

10.1 A Regulatory Impact Assessment has been prepared for this instrument as this will allow more people to obtain driving licenses without affecting road safety. It is estimated that up to 3000 people, as referred to in paragraph 7.14, may benefit from the social, domestic and economic benefits that driving brings Also businesses needing to employ vocational drivers will have a larger pool of prospective employees to choose from. Where current GB standards are being clarified a marginal road safety benefit is expected. This has no impact on charities or voluntary bodies.

10.2 The impact on the public sector is that DVLA will have to pay for the medical examinations for these applicants. $\pounds 266,000$ has been allowed for this in the current financial year.

10.3 An impact assessment is attached to this Memorandum.

11. Regulating small business

11.1 The legislation does not directly affect small businesses. Haulage and coach companies may have a larger pool of employees to choose from.

12. Monitoring and review

12.1 When UK made its 2010 notification to the European Commission, it was indicated that we would forward any amended legislation to adopt options to clarify or relax standards. Therefore, the European Commission will, in due course, be sent a copy of the legislation and a transposition table by way of update.

12.2 The Secretary of State must conduct a review of the operation and effect of these Regulations and publish the results before 15th November 2016.

13. Contact

Mark Davies at the Driver and Vehicle Licensing Agency Tel: 01792 783981 or e-mail: Mark.Davies@dvla.gsi.gov.uk can answer any queries regarding the instrument.

DEPARTMENT for TRANSPORT

Transposition Table for Diabetes Mellitus

91/439/EEC on driving licences and Commission Directive 2009/1113/EC amending Commission Directive 2009/112/EC of 25 August 2009 Amending Council Directive Directive 2006/126/EC of the European Parliament and Council on driving licences

NB Unless otherwise stated:

Any reference to a "section" means a section number of the Road Traffic Act 1988 ("the Traffic Act")

Any reference to a "regulation" means a regulation in the Motor Vehicles (Driving Licences) Regulations 1999 ("the principal Regulations").

current Medical Standards of Fitness to Drive' Any reference to "At a Glance" means the DVLA issued 'At a glance Guide to the Any reference to an "amending regulation" means a regulation contained in the Motor Vehicles (Driving Licences)(Amendment) Regulations 2011("the 2011 Regulations")

Existing EU Provision	New Provision in 2009/112/EC and 2009/113/EC	Objectives	Domestic Provisions
Currently no EU provision, save for that below.	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.	To provide a definition of "severe hypoglycaemia" and "recurrent hypoglycaemia".	This new EU definition of "severe hypoglycaemia" is inserted into regulation 72(7) and regulation 73(6E) of the principal Regulations by regulations 2(2) and 3(2) of the 2011 Regulations. Since the EU definition of "recurrent hypoglycaemia", being "two or more episodes of hypoglycaemia during a period of 12 months" is relevant to Group 1 only, the expression "two or more episodes of hypoglycaemia during a period of 12 months" is incorporated into regulation 72(4)(a) of the principal Regulation 2(2) of the 2011 Regulations
Group 1 10. Driving licences may be issued to, or renewed for, applicants or drivers who have diabetes mellitus, subject to authorised medical opinion and regular medical check ups appropriate to each case.	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	Ensures applicants and drivers with diabetes mellitus which is treated with medication are medically review by an authorised medical person at least every five years.	The 'At a Glance' guide advises that diabetes treated by diet does not require notification to DVLA. For those treated with medication, patients have to meet regularly with their GP in order to obtain their medication in the UK (at least 12 monthly).

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10.2 Driving licences shall not be issued to, nor renewed for, applicants or drivers who have recurrent severe hypoglycaemia or/and impaired awareness of hypoglycaemia.		years.
To restrict those who have two or more episodes within 12 months of hypoglycaemia that requires the assistance of another person and those who have impaired awareness of hypoglycaemia, from holding a licence.		
Regulation 72 of the principal Regulations is amended by regulation (2)(2) of the 2011 Regulations, by inserting paragraph (4) which makes recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia a relevant disability for the purposes of section 92(2) of the Traffic Act.	 see regulation 72(5)(c)of the principal Regulations, as inserted by regulation 2(2) of the 2011 Regulations. By virtue of section 99(1)(b) of the Traffic Act, such licence holders cannot be issued with a licence for longer than 3 years. For Group 1 licence holders who are treated with medication which carries a risk of inducing hypoglycaemia but which is not insulin, "At a Glance" requires notification to DVLA and licence reviews do not take place. 	Licences are only issued to those treated with insulin subject to statutory conditions, including a condition for regular medical review

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the issuing/renewal of group 2 licences to drivers with diabetes mellitus. When treated with medication which carries a risk of inducing hypoglycaemia (that is, with 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	10.2 A driver with diabetes should demonstrate an understanding of the risk of hypoglycaemia and adequate control of the condition.
diabetes mellitus (regardless of how it is treated) the opportunity to apply for a group 2 licence provided they can meet the specified criteria.	Ensures that only those who understand the risk of hypoglycaemia and have adequate control of hypoglycaemia are issued with a licence.
Regulations is amended by regulations 3(2) of the 2011 Regulations. A Group 2 licence can only be issued to a person treated with medication which carries a risk of inducing hypoglycaemia, subject to statutory conditions, which mirror the list of conditions in this paragraph 10.1 of the Annex to the Medical Directives. These are set out in paragraphs (6A) to (6D) of regulation 73 of the principal Regulations, as amended.	Regulation 72 of the principal Regulations is amended by regulation (2)(2) of the 2011 Regulations. In particular, this requirement is transposed by new regulation -72(5)(b) and (6).

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to driving, should be reported and should give rise to a reassessment of the licensing status.';	10.4 A severe hypoglycaemic event during waking hours, even unrelated							review, undertaken at intervals of not more than three years.	authority and to regular medical	licences should be issued subject to	10.3 Moreover, in these cases, such	complications of diabetes.
hypoglycaemic event which requires the assistance of another person.	To review the entitlement to a driving licence after any					issued.	years and requires a favourable opinion on whether a licence can be	medical review by a competent medical authority at least every three	hypoglycaemia have to undertake a	those treated with medication which	In order to be issued with a licence	
report any relevant or prospective disability; or to report if such a disability previously disclosed becomes more acute. Since any episode of severe hypoglycaemia in	Section 94(1) of the Traffic Act already requires a licence holder to	to issue licences limited to one year and hence the medical review will also be one yearly.	holders treated with insulin, discretion will be exercised under section 99(1A)(c) of the Traffic Act	yearly as a statutory minimum. However, "At a Glance" guidance is that in the case of Group 2 licence	for a medical review before issue of a licence is implemented at least 3	years, by virtue of section 99(1A)(c) of the Traffic Act , the requirement	(6D) can only be issued with a licence for a maximum period of 3	2011 regulations. Since persons within scope of regulation 73(6C)or	amended by regulation $3(2)$ of the	regulation $73(6C)(a)$ and $(6D)(a)$ of	This condition is set out in	

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	the previous 12 months wo rise to a relevant disability (regulation 73(6)(a) of the Regulations, as amended b regulation 3(2) of the 2011 Regulations), there could b doubt that a severe hypogly event must be reported, or person may be guilty of an under section 94(3) of the Act.	
	the previous 12 months would give rise to a relevant disability (regulation 73(6)(a) of the principal Regulations, as amended by regulation 3(2) of the 2011 Regulations), there could be no doubt that a severe hypoglycaemic event must be reported, or else the person may be guilty of an offence under section 94(3) of the Traffic Act.	
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