Driver & Vehicle Licensing Agency

Driver Services

Annex A:
Post-Implementation review of the Motor Vehicles (Driving Licences) (Amendment) Regulations 2011

Interactive document
April 2017

CUSTOMER SERVICE EXCELLENCE CSE

INVESTORS IN PEOPLE | Silver Until 2019

Simpler | Better | Safer

Driver and Vehicle Licensing Agency (DVLA)
Longview Road
Morriston
Swansea
SA6 7JL

1. Introduction

This document is the Post Implementation Review (PIR) of the UK's transposition of the European Commission Directives 2009/112/EC and 2009/113/EC into UK law through the Motor Vehicles (Driving Licences) Regulations 2011 SI No. 2516 ('The 2011 Regulations').

The PIR consists of four subsequent sections outlining the policy background, the background to the PIR, the available evidence and the PIR recommendation.

2. Policy background

2.1. Legislative background

For many years, domestic UK legislation has provided controls on the issue of driving licences to people with medical conditions, including diabetes, that are likely to compromise their ability to drive safely. The rules have always endeavoured to keep pace with latest medical opinion and the development of treatments to achieve the optimum balance between road safety and the ability for individuals to continue driving. The rules were based on European Council Directive of 29 July 1991 on driving licences (91/439/EEC), which required the common European Union driving licence model to be adopted by the Member States as the single driving licence model. Annex III of the directive specified the minimum standards required for the licensing of drivers. The directive came into force in the UK on 1 January 1997.

In its resolution of 26 June 2000 the Council asked for a review of the medical standards for driver licensing set out in Annex III to the 1991 directive. In addition to the on-going consideration of road safety and developing best practice on medical treatments, the review was motivated by the risk that the existence of different requirements in Member States could affect the principle of free movement.

In line with this council resolution, the commission advised that Annex III should be adapted in line with current scientific and technical progress. Diabetes was identified as one of the medical conditions affecting fitness to drive that needed further consideration. The Diabetes Working Group, established by the committee on driving licences, concluded that those developments should be taken into account by updating those provisions. The European Commission's Driving Licence Committee considered amendments to the standards and adopted revised minimum medical standards on 25 August 2009 in the form of directives: 2009/112/EC and 2009/113/EC ('the medical directives').

The Medical Directives amended the existing EU driving directives 80/1263/EEC, 91/439/EEC and 2006/126/EC, which had progressively introduced the broad framework for driver licensing, testing and the required medical standards for individual drivers across Member States[1]. They addressed issues in Directives 91/439/EEC and 2006/126/EC respectively and acknowledged that the minimum standards for fitness to drive were not harmonised to the full extent, and that member states are allowed to impose standards that are stricter than the minimum European requirements. The medical directives make specific provision for medical standards relating to eyesight, diabetes mellitus and epilepsy.

Member States were obliged to bring the directives into force and as such in November 2011 the Driver and Vehicle Licensing Agency (DVLA) introduced via Statutory Instrument (The Motor Vehicles (Driving Licences) Regulations 2011 SI No. 2516) the amended minimum medical standards required for driving with diabetes mellitus ("diabetes") .

The key objectives of transposing the directive into UK law were to apply the latest thinking of medical experts across Europe and to ensure the UK could meet its EU obligations to underpin the principle of mutual recognition, thereby providing mutual confidence that drivers across Europe meet an agreed standard of fitness.

2.2. Changes brought about by the regulations

The regulations made four changes to the minimum medical standards for driving with diabetes affecting both Group 1 (motorcycle and car) and Group 2 (lorry and bus) licence holders. Three of the changes raised the minimum standards required to licence drivers, while the fourth amendment relaxed the rules in respect of the requirements for the licensing of Group 2 licences.

[1] More details on these directives can be found in section 6.

[2] Regulations covering eyesight and epilepsy were introduced in February 2013 and will be the subject of a separate review by February 2018.

Figure 1: Changes brought about by the 2011 regulations

	Before the regulations	After the regulations
Group 1 drivers recurrent hypoglycaemia and impaired awareness	Licences are withdrawn from drivers with recurrent hypoglycaemia and/or impaired awareness of their condition.	Licences are withdrawn from drivers with recurrent hypoglycaemia Recurrent hypoglycaemia more precisely defined as being two episodes in 12 months. Drivers with impaired awareness are required to cease driving, until awareness has been re-gained. Driving licences shall not be issued to, nor renewed for, applicants or drivers who have impaired awareness of hypoglycaemia NB. The amendments did not provide for the relevance of hypoglycaemia occurring during sleep. See 4.4.4
Treatment with medication – Group 1 drivers	Only Group 1 drivers whose diabetes is treated with insulin are required to notify DVLA. Group 1 drivers treated with medication were not required to notify DVLA unless there is some other complicating aspect, for instance developing hypoglycaemia or a visual field defect.	Even tablet treated drivers who do not suffer complications must be subject to regular medical review at least every 5 years. In the UK, NHS guidelines mean that a doctor should not prescribe medication indefinitely without reviewing the patient at least every 12 months. Thus we implemented this requirement by making a slight amendment to the letter issued to Group 1 drivers with tablet treated diabetes. They will not be required to notify DVLA on an ongoing basis provided these regular prescription reviews or some other type of medical review are taking place.
Insulin treated diabetes – Group 2 drivers	Group 2 drivers with insulin treated diabetes were considered in exceptional cases for eligibility to drive only vehicle category C1 (a goods vehicle which has a maximum authorised mass (MAM) between 3.5 tonnes and 7.5 tonnes with a trailer up to 750kg). Such cases are subject to annual review. Drivers treated with insulin were not to be considered for licensing in any other Group 2 category of vehicle.	Drivers treated for diabetes, which carries a risk of hypoglycaemia (that is, with insulin and some tablets), may apply for entitlement to drive all Group 2 categories provided the following specific criteria are met: • there has not been any severe hypoglycaemic event 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

Continued overpage

		• the driver must demonstrate an understanding of the risks of hypoglycaemia, and • there are no other debarring complications of diabetes. DVLA applied the amending directives for insulin treated diabetes subject to annual review by an expert diabetologist to support the consideration of relicensing. This annual review requirement is slightly more stringent than the EU minimum requirement of a three yearly review, but the Secretary of State's Honorary Medical Advisory Panel on diabetes felt that it was necessary, for road safety reasons, to maintain the UK one yearly review currently required for limited C1 licensing. For diabetes treated with medication other than insulin which carries a risk of inducing hypoglycaemia the panel recommends accepting a doctor's report. This has enabled drivers with diabetes treated with insulin the same opportunities as other drivers with diabetes when applying for a licence. The amendment to regulations is generally a relaxation of the previous standard widening access to Group 2 driving for people with diabetes.
Severe hypoglycaemia	Prior to the amending directive drivers were required to report any significant change in condition. This would give rise to a reassessment of the licensing status and in particular frequent hypoglycaemic episodes likely to impair driving will lead to revocation.	The amending directive specified that a severe hypoglycaemic event during waking hours, even unrelated to driving, should be reported and should give rise to a reassessment of the licensing status. Whilst current UK regulations and guidance were compatible with the EU standard, we provided administrative clarity to make it clear that a severe hypoglycaemic episode even when not driving will lead to a reassessment.

3. Post-Implementation Review background

3.1. The PIR requirement

Regulation 4 of The Motor Vehicles (Driving Licences) (Amendment) Regulations 2011 SI N0 2516 introduced the duty to review SI 2011/2516 every 5 years (due by 14 November 2016).

3.2. Proportionality assessment for the PIR

In assessing the level of evidence that would be considered proportionate, the agency considers that the regulations are low risk and likely to have a low impact, as a relatively minor adjustment to existing measures that were already designed to ensure that people with a diabetic condition were only allowed to drive if there was reasonable confidence that they were safe to do so. The changes were not expected to result either in a significant number of people losing or regaining their entitlement to hold a licence. The regulations merely sought to apply the latest thinking of medical experts in Europe as well as those in the UK sitting on the Secretary of State's Honorary Medical Advisory Panel, in reaching a fair decision in each individual case.

Given this, the PIR follows a low evidence approach.

3.3. PIR approach

A small team from the DVLA Strategy, Policy and Communications Directorate was allocated to conduct the review with some occasional support from Business Support Teams and the Analytics Team. The approaches used are outlined in Figure 2.

Figure 2: PIR approaches

Approach	Detail
Stakeholder engagement	There is ongoing stakeholder engagement between DVLA and the key organisations representing diabetic drivers – Diabetes UK; the Independent Diabetes Trust; as well as road safety lobbyists and industry groups such as the Freight Transport Association, the Road Haulage Association and the Confederation of Passenger Transport. These links have been used to inform the PIR. Views have also been sought from a selection of Member States (Germany, Netherlands and Sweden) to provide a cross-section of different EU Member States approach to the directive.
Official correspondence	The DVLA has conducted informal analysis of ministerial and official correspondence
Monitoring data	The DVLA has some data showing the number of licence applications refused on the basis of a diabetic condition.

This PIR considers the general effectiveness of the regulations in transposing the 2009 directives into UK law in terms of the Secretary of State's ability to make appropriate decisions on individual motorist's suitability to hold a driving licence. This should maintain public confidence that there is an appropriate balance between road safety standards and an individual's freedom to be able to drive.

Given the low evidence approach, the review has not attempted to set out a monetised or numerical cost benefit analysis of the impacts on society and individual drivers as a result of the decisions made under the new regulatory regime. Neither has there been any attempt to measure the impacts of the regulations regarding the wider objectives of the directive in respect of the free movement of individuals between Member States and the mutual recognition of driving licences.

4. Evidence base

4.1. Policy objectives and intended effects

The objectives of the medical directives were to introduce revisions to the medical standards to reflect scientific and technical progress in this field.

4.2. Original impact assessment of the regulations

Although they were not objectives of the regulations, the impact assessment tried to assess the potential numbers of the people that would be affected by the four changes to the criteria to be applied to the issue of driving licences when a diabetic condition was a factor. In making that estimate, the IA also attempted to anticipate the likely costs that might arise. However, because these were not specific objectives no attempt was made to measure the actual costs and benefits that actually occurred. The estimates were based on the following logical assumptions:

- Where UK standards already meet EU standards there will be no impact on individuals, businesses or the third sector.
- Where UK standards are relaxed, we will remove current restrictions and a greater number of individuals may apply for or obtain a licence.
- Where UK standards are retained some individuals will continue to be prevented from driving.
- Where UK standards are raised to comply with EU minimum standards more people are likely to be prevented from holding/retaining a licence.

The original impact assessment estimated the costs to the DVLA of the regulation over 10 years as £1.75m in 2011 prices and the benefits as £0.15m over the same period. The costs related to re-issuing guidance materials and forms as well as paying for medical examinations for insulin treated group 2 drivers. The benefits related to reductions in processing costs for DVLA following the expected reduction in licence applications.

The impact assessment also noted some potential non-monetised benefits to road safety and to individuals that couldn't previously obtain a licence but became eligible following the introduction of the regulations.

4.2.1. Options within the directives

The requirements of the directives in respect of diabetes were quite specific, thereby limiting the options available. However, there was an element of flexibility in the finer details that were applied to ensure that the regulations implemented met the terms of the directive and were consistent with the views of the Secretary of State's Honorary Medical Advisory Panel.

Figure 3: Options available within the directives

	Options available	Option taken
Group 1 drivers	The amending directives required that diabetic drivers with an impaired awareness of their condition should cease driving until awareness has been restored. In terms of the increased standards, the policy intention was specific to improving road safety by reducing the risk of road accidents by drivers vulnerable to further hypoglycaemic attacks. However, the amending directive also allowed for the option for a licence to be granted once control or awareness (of the condition) is re-established.	DVLA chose to continue to maintain this option in the UK rules.
Group 2 drivers	The amending directives specified that drivers treated for diabetes, which carries a risk of hypoglycaemia (that is, with insulin and some tablets), may apply for entitlement to drive all Group 2 categories provided the following specific criteria are met: • there has not been any severe hypoglycaemic event 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, and, • there are no other debarring complications of diabetes.	DVLA applied the amending directives for insulin treated diabetes subject to annual review by an expert diabetologist to support the consideration of relicensing. This annual review requirement is slightly more stringent than the EU minimum requirement of a three yearly review, but the panel felt that it was necessary to maintain the UK one yearly review currently required for limited C1 licensing, for road safety reasons. For diabetes treated with medication other than insulin which carries a risk of inducing hypoglycaemia the Panel recommends accepting a doctor's report. This has enabled drivers with diabetes treated with insulin the same opportunities as other drivers with diabetes when applying for a licence.

4.2.2. Transposition of the directives

Transposition of the medical directives was completed primarily through the Motor Vehicles (Driving Licence) Regulation 1999 (as amended) and administratively via the 'at a glance guide' to medical practitioners and revised staff guidelines.

The amending directive should have been in place by August 2010 but the UK did not meet this deadline in terms of amending regulation, however the measures were in place administratively. Once the legislation took effect on 15 November 2011 the administrative guidelines/changes were fully in place and stakeholders informed. The regulations came into force with immediate effect.

4.2.3. Awareness raising, monitoring and enforcement

The new regulations were discussed with stakeholders throughout the process and their introduction was widely publicised. Individuals and stakeholders urged ministers to expedite implementation of the regulations to enable some Group 2 licences to be issued as soon as possible. There was a good deal of social media and press speculation as to the impact of tighter standards on Group 1 drivers, but actual transaction levels relating to second hypoglycaemic attacks have not shown the dramatic increase that some people feared. Ongoing engagement with stakeholders and individual drivers has ensured that the issue has remained a high priority in discussions with medical experts and EU counterparts.

4.3. Evidence of effects

4.3.1. Effects on drivers

The total number of Group 2 drivers with insulin treated diabetes is currently 18,253 (as of 21/5/2016). Prior to the relaxation of the Group 2 medical standards these drivers would not have eligible for Group 2 licence entitlement.

The total number of drivers revoked (deemed medically unfit to hold a licence) due to a diabetic condition is shown below. It can be noted that the number of revocations spiked in 2012 post the November 2011 introduction of the new rules before a levelling in the totals for 2013 to date.

Figure 4: Drivers revoked/refused directives

Time period	Drivers
2010	113
2011	515
2012	1,199
2013	864
2014	694
2015	811
2016 (Jan to August)	558

Source: DVLA

4.3.2. Effects on DVLA

It was estimated that the cost of amending forms and leaflets to cater for changes to regulations on epilepsy, eyesight and diabetes would be about £100,000. £30,000 of this amount was attributed to the diabetes changes.

Additionally, when an individual notifies a prospective disability, Section 94 (9) of the Road Traffic Act 1988 requires the Secretary of State/DVLA to pay the cost of any subsequent investigation by a doctor. Fees for medical examinations are not uniform and are set by individual medical practices or centres.

The medical examination costs in 2011 were assessed at £266,000[3] on the basis of 2,000 applications at £133 each, but actual costs have never been recorded for specific conditions. Fresh estimates have been made reflecting the cost of diabetic medical examination referral letters to consultants (£136.50) and General Practitioners (£85), from 2013 to date. The estimates are in Figure 5 and are broadly in line with the original IA estimate.

[3] As recorded in the original Impact Assessment

Figure 5: Medical examination costs

Time period	Consultant examinations	GP examinations	Total
2011	Not known	Not known	£266,000
2012	Not known	Not known	Not known
2013	£149,467	£88,570	£238,037
2014	£185,503	£86,530	£272,033
2015	£149,467	£88,570	£280,862

Source: DVLA estimates

4.3.3. Effects on firms

The relaxation of Group 2 standards meant that Group 2 drivers (of lorries and buses) are now eligible to be considered to apply for a licence if they are insulin dependent diabetics. This may benefit the road haulage and passenger transport industry.

4.3.4. Unintended effects

The regulations have the effect of barring individuals that suffer 'night time hypos' from driving. This could be considered an unintended effect as drivers who experience hypoglycaemic attacks only during sleep, and who otherwise manage their condition well, are unlikely to present any risk to road safety. As a result, the UK has campaigned to change EU legislation on this item and DVLA has played a leading role in campaigning on behalf of the UK. More details can be found in section 5.2.

4.4. Limitations of the evidence base

The evidence base is constrained by the limited availability of monitoring data that would allow effects of the regulations to be more robustly identified.

Responses from industry stakeholders have been limited in content particularly in regard to unintended consequences, however that of course may reflect the view that the industry are content with the impact of the change particularly in respect of Group 2 drivers with diabetes.

Responses from Member States have been limited to how they have implemented the changes in terms of their countries administrative processes and legislative implementation. No indication was given to illustrate how different countries have implemented the directive in different ways. However, there has been wide support from other Member States for the measure to amend the unintended outcome regarding hypoglycaemic attacks whilst asleep.

4.5. Recommendations for future impact assessments

An apparent weakness of the impact assessment was the lack of a plan to collect data to measure the anticipated costs and benefits. However, these outcomes were low level and they were not the primary purpose of the regulatory changes. Future assessments will consider the need to collect appropriate and proportionate data to support measurement of the actual outcomes.

5. PIR recommendation

5.1. Overall recommendation

It is recommended that the regulations should remain in place except for the matter of those people caught by hypoglycaemic attacks whilst asleep. The UK has already taken steps to make changes through the EU Commission's Regulatory Fitness Programme (REFIT) as outlined below.

5.2. Next steps for the regulation

As mentioned in section 4.3.4, the regulations have the effect of barring individuals that suffer 'night time hypos' from driving. This could be considered an unintended effect as drivers that only experience hypos during sleep are unlikely to present any risk to road safety. Supported by leading stakeholders the UK has campaigned to amend EU requirements on this item.

The DVLA has pressed for changes on behalf of the UK. The issue was raised as a priority through REFIT (the EU Commission Regulatory Fitness Programme) and the EU Commission agreed it could be added to the agenda for the June 2015 Driving Licence Committee. To aid that discussion, DVLA drafted a paper setting out the issue and a proposed legal text. A DVLA medical adviser provided a presentation on the subject at the June Driving Licence Committee and also chaired a European Diabetes Working Group in September 2015 to agree a proposed legal text.

The main aim of the proposed change is to differentiate between episodes of severe hypoglycaemia during waking hours and those whilst asleep. Severe hypoglycaemia means that the assistance of another person is needed. The view of DVLA medical experts is that hypoglycaemia should not be classified as severe when it occurs during sleep because it is more difficult to recognise the warning symptoms and to treat the event appropriately.

The UK also proposed a reduction in the current bar for drivers who had experienced two or more episodes of severe hypoglycaemia in a 12 month period. DVLA medical experts feel this time span is no longer medically justified and a 3-6 month bar on driving after the most recent episode of severe hypoglycaemia would be a more appropriate duration, with the option of a longer period if medical advice recommends it.

The proposals were received positively at a recent European Driving Licence Committee and referred for examination and scrutiny. The proposed amendments were accepted on 19 February 2016.

The directive for the amendment to the medical Annex (2016/1106) was published on 8 July 2016 and shall come into force on 1 January 2018.

Strategy, Policy and Communications Directorate

DVLA
Longview Road
Morriston
Swansea
SA6 7JL
gov.uk/dvla

OOJ/17/051
4/17