Title:	
European Proposals to amend Driving Licence Standards for Diabetes. Annex III of Directive 91/439/EEC **Lead department or agency:** Department for Transport **Other departments or agencies:** DVLA	**IA No:** DFT00010 **Date:** 01/01/2010 **Stage:** Development/Options **Source of intervention:** EU

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Certain categories of diabetes adversely affect the ability to drive safely. All EU Member States must issue driving licences in compliance with minimum medical standards. Existing minimum standards for diabetes in Annex III to Directives 91/439/EEC and 2006/126/EC are revised by new standards in Directives 2009/112/EC and 2009/113/EC with effect from 25 August 2010. Member States cannot have less than the minimum but may apply or retain higher than the minimum standard if justified.

What are the policy objectives and the intended effects?

The Directive specifies minimum standards for four categories of diabetes that affect the UK.
The policy objectives are to increase current UK standards if obliged to in order to comply with the minimum standard on the directive, to relax current UK standards (and align with the dreictive) thus removing exisiting restrictions on drivers, and where medical opinion advises to retain existing UK standards. The intended effect is to allow those with the specified condition access to driving as far as the directive permits.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

In three of the four categories for diabetes current UK standards are below that required by the Directive. We are obliged to change the standard so that the UK is compliant. In the fourth category we propose relaxing the existing UK standard and therefore align with the directive's minimum standard. The Secretary of State's Honorary Medical Advisory Panel (the Panel) on diabetes has considered the proposed changes and has advised whether in its opinion a relaxation of the current UK standard would compromise road safety.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 08/2013
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

SELECT SIGNATORY Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY:..... Date:.....

Summary: Analysis and Evidence

Policy Option 1

Description:

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
	2005	10	**Low:** Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	na		na	**£0.02**
High	na		na	**£0.12**
Best Estimate	£0.09		na	**£0.07**

Description and scale of key monetised costs by 'main affected groups'

There are monetised costs of re-issuing guidance material and forms in line with the new standards. This will be a one off cost, estimated at £100,000, which will cover all the changes to guidance regarding vision, diabetes and epilepsy.

Other key non-monetised costs by 'main affected groups'

As three of the current diabetes standards will be tightened, some licence holders may lose their licences with the associated loss of the social, domestic and economic benefits that driving brings. We have estimated that between 705 and 1,410 drivers may be adversely affected. These are based on the assumption that either 0.05 percent or 0.1 percent of medically restricted licence holders with diabetes could be affected.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	na		£0.01	**£0.1**
High	na		£0.03	**£0.2**
Best Estimate	na		£0.02	**£0.16**

Description and scale of key monetised benefits by 'main affected groups'

There are monetised benefits to DVLA from processing less licence applications as a result of the tightened restrictions. These savings have been estimated at between £14,100 and £28,200.

Other key non-monetised benefits by 'main affected groups'

One of the current diabetes standards will be relaxed allowing more people to obtain driving licenses without affecting road safety. We have estimated that between 235 and 470 people may benefit from the social, domestic and economic benefits that driving brings. Where UK standards are being raised we would expect a marginal road safety benefit. These assumptions are based on 0.05 percent or 0.1 percent of medically restricted licence holders with diabetes will be affected.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

No figures are available for the number of people affected by each specific diabetes category. We have provided indicative estimates of the number of people who may be affected by the changes to the minimum standards. These are based on the assumption that either 0.05 percent or 0.1 percent of medically restricted licence holders with diabetes problems will be affected.

Impact on admin burden (AB) (£m):			Impact on policy cost savings	In
New AB: na	**AB savings:** na	**Net:** na	**Policy cost savings:** na	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			25/08/2010		
Which organisation(s) will enforce the policy?			DVLA/DVA/DSA/Police		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medi um**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	Yes	9
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	9
Small firms Small Firms Impact Test guidance	Yes	9
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	Yes	9
Wider environmental issues Wider Environmental Issues Impact Test guidance	Yes	9
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	9
Human rights Human Rights Impact Test guidance	Yes	9
Justice system Justice Impact Test guidance	Yes	9
Rural proofing Rural Proofing Impact Test guidance	Yes	9
Sustainable development Sustainable Development Impact Test guidance	Yes	9

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	diabetes_and_driving_in_europe_final_1_
2	"Directive 2009 112 EC.pdf"
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	0.09									
Annual recurring cost										
Total annual costs	0.09									
Transition benefits										
Annual recurring benefits	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office Excel Worksheet

Evidence Base (for summary sheets)

Background

Current driver licensing and testing rules in the UK are based on the requirements of the second European Council Directive on driving licences (91/439/EEC). That Directive harmonised rules throughout the European Economic Area for the mutual recognition and exchange of Member State licences, and specified minimum medical and testing standards that should be applied for the issue of driving licences.

In recent years officials and medical experts drawn from across the European Union have reviewed the standards for diabetes. Following receipt of their reports the European Commission's Driving Licence Committee considered amendments to the standards and published revised minimum standards on 25 August 2009 (references: 2009/112/EC and 2009/113/EC) to come into effect by 25 August 2010.

The Secretary of State's (SoS) Honorary Medical Advisory Panel (the Panel) on diabetes has considered the proposals in detail and have provided expert advice on the interpretation of the revised standards. The proposals set out here are consistent with the recommendations of the Panel and supported by DVLA who believe that road safety will not be adversely affected by the relaxation of some current UK standards.

The Directive recognises two groups of drivers:-

Group 1 *(cars and motorcycles)* - relates to vehicle categories A and B. These include 2 or 3–wheeled vehicles, cars and light vans up to 3.5 tonnes.

Group 2 *(buses and lorries)***-** relates to vehicle categories C, and D (and their sub categories of C1 and D1) these include medium and large lorries and buses. The medical licensing standards for lorry and bus drivers are more stringent than for Group 1 drivers. The processes and higher medical standards aim to balance the additional risks to road safety presented by the size and weight of the vehicles being driven and the greater time the driver may spend at the wheel in the course of their occupation.

Impact from the directive

In many cases current UK standards already meet EU minimum standards; therefore we are already compliant with the directive and need to make no change. We have reviewed existing standards to assess whether, in the light of medical expert opinion, we should relax current UK standards and more closely align with EU minimum standards. The directive allows Member States to apply or retain a standard higher than the minimum European requirements if justified.

The impact of the directive means that certain criteria for the issue of a driving licence will change:

- Where UK standards already meet EU standards there will be no impact on individuals
- Where UK standards are relaxed, we 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 as at present to be prevented from holding a licence on reapplication.
- Where UK standards are raised in order to comply with EU minimum standards some individuals will be prevented from holding/retaining a licence when previously they were not

Consultation
This Impact Assessment (IA) forms part of a full public consultation process carried out in accordance with the 'Code of Practice on Consultations' issued by the Cabinet Office. The document is an initial Impact Assessment which may be enhanced by information provided by respondents to the consultation and from other sources. Some of the proposals may also be subject to further consultation in which case the IA will be subject to further review.

The Proposals
The Directive makes four proposals to the minimum medical standards for driving with diabetes. In three of the four the current UK standard is currently below the minimum required by the Directive and the UK is therefore obliged to change in order to be compliant. A change in the UK standard to meet EU requirements means that some applicants and existing drivers will be prevented from holding a licence. In the fourth category, we propose a relaxation of the current UK standard.

Definition of Diabetes
Diabetes is caused by the body's failure to produce insulin, a hormone released by the pancreas to help control levels of sugar in the blood.

Raising the UK standard to meet the Directive's requirements:

Proposal 1
Group 1*(cars and motorcycles)* – The Directive requires drivers or applicants experiencing recurrent severe hypoglycaemia shall not be issued with nor have their licence renewed.

Currently, UK standards allow Group 1 drivers who have had two or more episodes of severe hypoglycaemia (requires the assistance of another person) in a 12 month period, subject to expert opinion may be issued with a licence. We are obliged to raise the UK standard to meet with EU requirements.

Proposal 2
Group 1 *(cars and motorcycles)* **–** The Directive requires drivers or applicants who have impaired awareness of hypoglycaemia shall not be issued with nor have their licence renewed.

Currently, Group 1 drivers with impaired awareness may subject to expert medical advice be issued with a driving licence. We are obliged to raise the UK standard to meet with EU requirements.

Proposal 3
Group 2 *(buses and lorries)*– The Directive requires 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.

Currently Group 2 drivers who suffer more than one severe hypoglycaemic event within 12 months even unrelated to driving must report these to DVLA. The Directive requirement means that any severe hypoglycaemic event during waking hours, even unrelated to driving must be reported (in the UK's case to the DVLA or DVA) which would give rise to a reassessment of the licensing status. We are obliged to raise the UK standard to meet with EU requirements.

Relaxing the current UK standard:

Proposal 4
Group 2 *(buses and lorries)-* Drivers or applicants treated for diabetes, with medication, which carries a risk of hypoglycaemia (that is, with insulin and some tablets), may apply for entitlement to drive all group 2 category vehicles provided specific criteria is met.

Currently Group 2 drivers with insulin treated diabetes are only considered in exceptional cases to drive category C1 vehicles. The UK proposes to relax the existing UK standard so 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 category vehicles provided specific criteria is met.

Cost and benefits

There are approximately 1.9 million drivers on DVLA records holding medically restricted licences, of which diabetes accounts for 24.7 percent this equates to 470,337 people suffering from diabetes. To date, figures for different categories of diabetes have not been recorded, so it is impossible to know how many drivers will be affected by our proposals. Nor has it been possible to quantify the social, domestic and economic benefits of obtaining a driving licence. We therefore cannot accurately estimate the impact of the proposals. For illustrative purposes we have estimated the number of drivers who would be affected assuming either 0.05 percent or 0.1 percent of registered licence holders with diabetes could be affected. There is a positive impact on businesses who employ bus or lorry drivers as they will now be able to consider people who have diabetes treated with insulin to drive all group 2 category vehicles, where previously they couldn't.

Costs
The main monetised costs come from additional administration for the DVLA.

a) Forms and leaflets will need to be updated, including "At a Glance guide to the current medical standards of fitness to drive". The "At a Glance" guide is freely available on DVLA website. If an individual wishes to obtain a printed copy an administration fee of £4.50 is charged (during the last 12 months only 4 such copies have been requested.) The cost of updating forms and leaflets is covered by the central operational fund and is estimated to be £100,000. This cost will only be incurred once to cover the costs of updating the standards for vision, diabetes and epilepsy.

b) The cost of processing a driving licence on medical grounds is estimated to be approximately £30. The relaxation of one of the minimum standards will increase the number of such licences being processed. Again, we have indicatively estimated the increase in costs assuming either 0.05 percent or 0.1 percent of registered licence holders with diabetes could be affected. This would be an annual cost.

Benefits
Where it is proposed to relax the minimum standards this will lead to more drivers qualifying for licences. For illustrative purposes we have estimated the number of drivers who would be affected assuming either 0.05 percent or 0.1 percent of registered licence holders with diabetes could be affected.

The cost of processing a driving licence on medical grounds is estimated to be approximately £30. The tightening of three of the minimum standards will reduce the number of such licences being processed. Again, we have indicatively estimated the cost saving assuming either 0.05 percent or 0.1 percent of registered licence holders with diabetes problems is affected.

It is also expected that the tightening of certain minimum standards should improve road safety.

Table 1 summarises the change in the number of licence holders and application processing costs for each proposal under the assumption that either 0.05 percent or 0.1 percent of registered licence holders with diabetes problems is affected by each proposal.

Table 1

Proposal	**Change in number of licence holders**		**Change in application processing costs**	
	0.05 percent	**0.1 percent**	**0.05 percent**	**0.1 percent**
1	-235	-470	-£7,050	-£14,100
2	-235	-470	-£7,050	-£14,100
3	-235	-470	-£7,050	-£14,100
4	235	470	£7,050	£14,100
Total	**-470**	**-940**	**-£14,100**	**-£28,200**

Statutory Equality Duties Impacts
There is no race, gender, sexual orientation or, transgender implications resulting from the introduction of these new policies. On the disability issues, one of the proposals will allow drivers with diabetes treated with insulin to apply for a group 2 driving licence where as now they are prevented from doing so.

Competition Assessment
DVLA and DVA are sole licensing authorities in GB so competition guidelines do not apply. Annex III of the second Directive does not create the need for additional services that would be subjected to competitive tendering.

Small Firms Impact Test
Small companies will now be able to consider people who have diabetes treated with insulin to drive all group 2 category vehicles, where previously they couldn't.

Greenhouse Gas Assessment Impact Test
The introduction of these policies could potentially see an increase in the number of people who can obtain a licence, which could mean an increase in the number of vehicles on the road. The reverse is also applicable in that these policies could potentially see an increase in the number of people refused a licence, which could mean a reduction in the number of vehicles on the road. However, no figures are available on the number of people who would be affected.

Wider Environmental Issues Impact Test
There will be no adverse effects on the environment, but there will be no improvement either. There will be no harm to the landscape as a result of the introduction of these policies.

Health and Well-being Impact Test
One of the proposals would allow people who have diabetes treated with insulin to apply for a licence to drive all group 2 category vehicles, which will improve their mobility. This should improve their social, domestic and economic well-being.

Human Rights Impact Test
There is no human rights implications resulting from the introduction of these new policies

Justice Impact Test
There is no impact on justice resulting from the introduction of these new policies

Rural Proofing Impact Test
The introduction of the new minimal medical standards would be equally borne by rural and urban communities.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added to provide further information about non-monetary costs and benefits from Specific Impact Tests, if relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review]; Internal DVLA review of policy.
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] Link from policy objective to outcome.
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] Following consultation a summary analysis report is completed.
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] Monitor the database to identify if more or less people are driving with diabetes due to the introduction of the new EU standards.
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] N/A until final version of Impact Assesment completed.
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] Compare figures of drivers with diabetes in 2010 with those in 2013 (3 years).
Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here] N/A

Add annexes here.