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Report on Diabetes and Driving

Response by HM Government

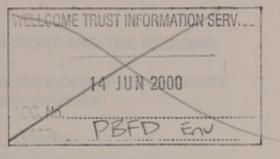
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DEPARTMENT OF THE ENVIRONMENT, TRANSPORT AND THE REGIONS

HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE INQUIRY INTO THE SCIENTIFIC ADVISORY SYSTEM:

REPORT ON DIABETES AND DRIVING

RESPONSE BY HM GOVERNMENT

- 1. The Advisory Panel on Diabetes and Driving is one of several panels of medical experts set up by the Secretary of State to provide medical expertise in relation to certain medical conditions and ability to drive. Its members have provided advice on risk assessment based on their expert knowledge, usually as practising consultants of many year's standing, to the Driver and Vehicle Licensing Agency. The work of panel members has continued, unpaid and largely unreported, since 1983. The Government acknowledges the considerable service offered by these members to the cause of road safety.
- 2. Two recent events have begun to change the way that policy is determined in relation to medical conditions and licensing of drivers. First has been the Second European Community Directive on Driving Licences, a document drawn up in the late 1980's, agreed by European Transport Ministers in 1991 and then required to be brought into domestic law in each member state by 1996. Like many directives, that document was derived from a set of principles drawn from varying practices in member states with the differences eliminated by negotiation and majority voting.
- 3. Second, since the advisory panels were set up in 1983, and the Second Directive on Driving Licences was agreed in 1991, there have been fundamental changes in the way that scientific principles are deployed and debated within Government. "Guidelines on the Use of Scientific Advice in Policy Making" were issued by the Chief Scientific Adviser, Sir Robert May, in 1997. More recently, the Modernising Government White Paper and the subsequent Action Plan have emphasised the importance of evidence-based policy making and the need for better use of evidence and research.
- 4. Several of the criticisms of the Select Committee that the Department's transposition of the Second Directive into domestic law was not based on evidence of risk assessment or scientific principles, and that the constitution of the advisory panel does not accord with the May recommendations need to be seen in the light of this timetable.
- 5. Subject to that preamble, the Government has found the Select Committee's report extremely instructive in its review of the advisory panels which it wishes to continue, and in relation to the development of policy in the area of diabetes and driving. Our detailed responses to the Committee's findings are as follows:
 - a. The UK's position on exceptional cases for renewing existing professional insulin-treated drivers' entitlements was to some extent based on the view of the Honorary Advisory Panel. That panel's view, however, was influenced by DETR advice that other member states were applying a ban. The DETR now concedes that "information turned out not to be accurate". We recommend that the Government refers this matter back to the Honorary Advisory panel for further consideration based on an understanding of practice in other EU countries.

The Government recognise that this area should be re-examined. The Panel, at the Department's invitation, has indicated its willingness to re-examine its advice on what constitutes "in very exceptional cases".

The Government acknowledges that the decision to impose a ban on renewing the C1 and D1 entitlements of pre-1997 car licence holders with insulin treated diabetes in part reflected the long-held view of the Advisory Panel that for the driving of heavier vehicles, there should be no "exceptional cases". It is to be remembered that the Second EC Directive stated that:

"Only in very exceptional cases may licences be issued to, or renewed for, applicants or drivers in this group [Group 2] suffering from diabetes mellitus and requiring insulin treatment . . ."

The same consideration dictated the policy that licences for entitlements C1 and D1 should not be granted to new applicants with insulin treated diabetes following implementation of the Directive in January 1997.

The Panel were not, however, responsible for brigading categories C1 and D1 with "heavier" vehicles. That stemmed from a combination of former UK practice, and the imperative of the Second EC Directive. The UK had no choice in the matter, given that the Directive did not provide for "grandfather rights". Nor was the issue put to the Panel at the time the regulations to implement the Directive were being made.

The matter was subsequently (November 1997) addressed by the Panel, in the light of growing concerns about the implications of the legislation that was to take effect the following January. The Department informed the Panel, on the basis of its understanding, that most other EU member states imposed a ban on issuing or renewing licences for Group 2 vehicles; in most member states there was not a separate D1 and C1 entitlement (use of which is optional) and the driving of such vehicles would be covered by the higher D and C entitlements. It subsequently came to light that a number of member states were allowing exceptional cases.

On obtaining more up-to-date (June 1998) information (included in the Department's evidence and replicated in the Committee's report) about the practice in other member states, the Department informed the Panel. In the light of the fact that most member states operated procedures for identifying "exceptional cases" for renewal of licences, the Panel felt able to relax their former position, but only in respect of the C1 entitlement.

So the regime which has been in operation since September 1998 for C1 vehicles was devised in the knowledge of the practice – in general terms – in other member states. The Department is currently trying to obtain more precise details of the arrangements which are in place in those member states which allow exceptions and also consulting the European Commission as to what practice is in line with the Directive.

b. We find the rules for medium-sized vehicles as they apply to insulintreated drivers illogical and inconsistent. We see no reason why the exception for voluntary drivers of minibuses should be extended to those who do not meet the required medical standards for driving larger vehicles.

The Government agrees that the position needs to be regularised, in consultation with the voluntary sector.

The Government accepts that, set against a ban on the normal driving of minibuses by those with insulin-treated diabetes, and restrictions on similar pre-1997 licence holders driving small lorries, permitting insulin-treated diabetics to drive minibuses as volunteers is illogical and inconsistent. This has not derived from advice from the Advisory Panel, which has consistently opposed the "volunteer" exception.

As was reported, the UK was instrumental in securing the volunteer minibus derogation, in order to avoid the burden of Group 2 licensing being placed on the voluntary sector. This was based on an understanding that, given that the volunteer sector acted responsibly, it was unlikely that there would be insulin-treated diabetics (or those with other medical conditions which would be a bar to driving minibuses ordinarily) who drove as volunteers and therefore no reason specifically to exclude such driving.

c. We consider that the exception for insulin-treated professional drivers of small lorries has been applied in an unacceptably arbitrary manner. We recommend that the overriding criterion which should be applied in determining whether or not any diabetic driver should obtain a Group II licence should be the risk of the driver being unaware of the onset of hypoglycaemia.

The Government notes the Committee's views.

It is not the case, however, that the criteria for renewing category C1 entitlements for those with insulin-treated diabetes is arbitrary. The legal requirement, as expressed in the Second EC Driving Licence Directive, and to which the UK is bound is, as quoted above "only in very exceptional cases". The Advisory Panel therefore sought to devise a scheme which would comply with this requirement. The scheme was aimed at minimising the risks to other road users. The Panel judged that only those who have demonstrated satisfactory management of their condition under demanding circumstances could be regarded as posing an acceptable level of risk and thus be treated as "very exceptional".

The inclusion in the criteria of a minimum number of hours spent driving was intended to distinguish between those who spent all or most of the working week driving lorries and those who drove lorries only occasionally. It was the latter group who were regarded by the Panel as the greater risk because such "occasional" drivers might be less aware of the effect of vigorous physical activity or stress on their metabolism and might also be less sensitive to warning symptoms of hypoglycaemia.

Nevertheless, as indicated in response to recommendation (a), the Department has invited the Advisory Panel to re-examine what constitutes "in very exceptional cases", as stipulated in the 2nd Directive. The Department must rely on the Advisory Panel's judgement on whether "being unaware of the onset of hypoglycaemia" is in practice a possible basis for driver licensing. In doing so the Department will ensure the Panel has access to risk assessment expertise.

d. We welcome the planned campaign to raise awareness of the need to declare medical conditions which may affect driving.

The Government welcomes the Committee's endorsement.

e. We recommend that clear terms of reference be drawn up for the Honorary Advisory Panel, setting out precisely its role in advising Ministers, the limits on the areas it should advise upon and the split between Panel, official and Ministerial responsibility.

Terms of reference for the Panel were under review at the time the Committee reported and have now been completed. A copy is attached for the Committee's information.

The Government notes the Committee's further suggestion about clearer delineation between the roles of officials and Ministers. Ministers determine public policy which is published in policy documents and, if necessary, defined in legislation approved by Parliament. The Department's Officials advise Ministers on policy and take decisions, on

behalf of Ministers, in accordance with policy. Members of Advisory Panels provide independent advice based on expert knowledge.

f. The current members of the Honorary Advisory Panel have the necessary expertise and experience in diabetes and insulin-induced hypoglycaemia.

The Government welcomes the Committee's acknowledgement of the Panel's expertise.

g. We recommend that the Government appoints an expert on road traffic accident statistics to the Honorary Advisory Panel on Driving and Diabetes Mellitus and considers similar appointments to the other Honorary Medical Advisory Panels.

The Government accepts this recommendation.

In relation to other Panels, consideration will need to be given to the appointment of a statistician or possibly an epidemiologist according to the nature of the problems presented.

h. The absence of lay membership on the Honorary Advisory Panel is unsatisfactory. We recommend that the Government appoints two lay members to this Panel and considers similar action in respect of the other Honorary Medical Advisory Panels.

In principle, the Government favours the introduction of a lay element in the formulation of policy advice on medical aspects of driver licensing.

There are two points of note. First the Panels were set up long before Sir Robert May's principles were elaborated. Second, their very specialised nature – dealing with detailed medical assessments both generally and in relation to individuals – presents some issues of professional confidentiality which constrain open discussion.

The Government acknowledges that lack of transparency of such specialised advice, and lack of understanding of the basis of that advice can and does give rise to concern by those affected adversely by that advice.

The Government is also mindful of the benefits of including experts from fields other than medicine. Subject to this not vitiating the quality of technical advice on which the Department is dependent, the Government will consider, in conjunction with each Panel, how best to give effect to the spirit of this recommendation.

i. We recommend that the Government and the British Diabetic Association jointly identify an insulin-treated diabetic to attend meetings of the Honorary Advisory Panel as a non-voting member. While such an individual should not be as a formal member of the Panel, he or she should have full access to Panel papers and be invited to participate fully in discussions.

As with recommendation (h) the Government will consider, in conjunction with each Panel, how best to give effect to this recommendation. It is certainly our intention that policy in relation to medical conditions and driving is better understood by those affected.

j. The arrangements for appointment of members to Honorary Medical Advisory panels are unsatisfactory. We recommend that the Government establish a fixed term of appointment of no longer than five years, which should be renewable only once. Such a policy, although necessary to comply with the rules of the Commissioner for Public Appointments, should be implemented gradually so that continuity is maintained and to ensure that there is no large change in the Panel's membership at any one time.

<u>The Government agrees.</u> Appointments to Panels are made on the basis set out in this recommendation.

k. We recommend that the Honorary Advisory Panel publishes an annual report and, shortly afterwards, holds an annual meeting with the British Diabetic Association and other interested parties to discuss matters of common interest and to explain any complex recommendations made.

The Government agrees. This is an excellent suggestion that will be taken up with Panels.

 We recommend that the Honorary Advisory Panel's agendas are published in advance of meetings and that minutes be published shortly after meetings, with the privacy of any individuals discussed suitably protected.

The Government accepts this recommendation.

m. We recommend that the Government makes explicit the risk basis for road safety policy in respect of licensing of individuals with medical conditions which potentially affect fitness to drive.

The Government accepts this recommendation in principle.

There are two considerations. First, the medical standards for granting and renewing licences for driving different classes of vehicles are set out in the Second EC Driving Licence Directive, and incorporated in domestic legislation. It is difficult to depart from these without the danger of legal proceedings by the European Commission.

The second consideration is that in many cases – and specifically in the case of diabetes – it might take some time (possibly 2 to 3 years) before an authoritative calculus could be established on the basis of definitive research.

Nevertheless, the Government recognises the benefits in bringing clarity and transparency to the basis of its road safety policy, where that is practicable, and will institute the necessary work to enable the risk basis to be established.

n. The DETR states that independent UK evidence is unnecessary because the present policy and practices are derived from obligations to adhere to European legislation based on "long-standing expert assessment of the dangers associated with the driving of larger vehicles by insulin-treated diabetics". This assessment does not appear to be supported by any evidence. We recommend that the evidence basis for such expert assessment should be made publicly available.

The Government notes the Committee's views.

It is not open to the Government to refuse to comply with European legislation on the grounds that it is not supported by clear scientific evidence without risking infraction proceedings.

Nevertheless, as has been acknowledged in respect of recommendation (m), there would be benefits in making available, wherever possible, the evidence base for the risks associated with particular medical conditions. The Department will therefore take steps, in conjunction with the European Commission where possible, to obtain such evidence and make it available.

o. We recommend that the scope and depth of the Fitness to Drive Research Programme should be enhanced and adequately funded.

The Government welcomes the Committee's endorsement of the proposed research.

The programme will be developed to deliver the evidence needed, wherever possible, to support policy in this area.

p. We recommend that the Government reviews policy in the area of licensing procedures for insulin-treated diabetic drivers of Group II vehicles including an analysis of the feasibility of implementing the British Diabetic Association proposals for individual assessments.

The Government will review the arrangements as recommended.

The Committee will have noted the Government's intention to invite the Advisory Panel to re-examine the question of "very exceptional cases" as a starting point.

DETR

28 APRIL 2000

TERMS OF REFERENCE FOR THE DETR HONORARY ADVISORY PANEL ON DIABETES AND DRIVING

- 1. To advise the Secretary of State on medical policy aspects of the relationship between the ability to drive and diabetes.
- To advise the Secretary of State on individual cases, relating to the ability to drive with diabetes.
- To advise the Secretary of State on his published guidance on the ability to drive with diabetes.

DETR

April 2000









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