EXPLANATORY MEMORANDUM TO

THE DRUG DRIVING (SPECIFIED LIMITS) (ENGLAND AND WALES) (AMENDMENT) REGULATIONS 2015

[2015] No. [XXXX]

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

2. Purpose of the instrument

2.1 The instrument specifies amphetamine as a controlled drug (within the meaning given by the Misuse of Drugs Act 1971) for the purposes of drug driving and sets a limit in blood above which it will be an offence to drive. The legislation will therefore add amphetamine and its limit to the other 16 drugs and their limits that have already been specified in SI 2014/2868 'The Drug Driving (Specified Limits) (England and Wales) Regulations 2014'.

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

3.1 None

4. Legislative Context

4.1 Section 4 of the Road Traffic Act 1988 "1988 Act" makes it a criminal offence to drive when under the influence of drink or drugs. The difficulties involved in proving impairment due to drugs means that section 4 is not often used in drug driving cases. Section 5 of the 1988 Act makes it an offence to drive or be in charge of a motor vehicle with a concentration of alcohol in the body above the prescribed limit.

4.2 Section 56 of the Crime and Courts Act 2013 inserted a new section 5A into the 1988 Act, which makes it an offence to drive with a blood concentration level above the specified limit for a specified controlled drug. SI No 2868 'The Drug Driving (Specified Limits) (England and Wales) Regulations 2014' specifies 16 such drugs and corresponding limits, and this instrument now adds amphetamine and the limit for the purposes of the section 5A offence.

4.3 The Misuse of Drugs Act 1971 prohibits the production, import, export, possession and supply of "controlled drugs" (subject to regulations made under the Act).

4.4 Amphetamine, which is specified in this instrument, is a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 and is listed in Schedule 2 to that Act.

5. Territorial Extent and Application

5.1 This instrument extends to England and Wales.

5.2 The regulation-making power in new section 5A of the 1988 Act is exercisable by Scottish Ministers in relation to Scotland.

6. European Convention on Human Rights

6.1 The Parliamentary under Secretary of State, Robert Goodwill MP, has made the following statement regarding Human Rights:

"In my view the provisions of the Drug Driving (Specified Limits) (England and Wales) (Amendment) Regulations 2015 are compatible with the Convention rights."

7. Policy background

- **What is being done and why**

7.1 In December 2009, Sir Peter North CBE QC was appointed by the then Secretary of State for Transport, to conduct an independent review of the law on drink driving and drug driving. Sir Peter North's *Report of the Review of Drink and Drug Driving Law* was published in June 2010 and made a variety of recommendations with regard to drink and drug driving, including that further consideration should be given to introducing a new specific offence of driving or being in charge of a motor vehicle with a concentration of a controlled drug above a specified limit. The *Report* also recommended including amphetamine in any new offence.

7.2 The Secretary of State for Transport made a written ministerial statement on 21st March 2011 (House of Commons, Official Report, column 44WS to 46WS) which announced the publication of the Government's response to the reports by Sir Peter North and the Transport Select Committee on Drink and Drug Driving (CM 8050). The response endorsed Sir Peter North's recommendation that the case for a new offence relating to drug driving should be examined further.

7.3 Fewer than 1,200 proceedings were brought in 2013 under the existing section 4 impairment offence, with the proportion of guilty findings from the proceedings from unfit through drugs at only around 72%. This is compared to the nearly 47,000 proceedings for the section 5 drink driving offence and the 96% proportion of guilty findings. European evidence from the Driving under the Influence of Drugs, Alcohol and Medicines (DRUID) project suggests drug driving is about half as prevalent as drink driving, so enforcement related to drug driving is disproportionately low.

7.4 The new section 5A offence has therefore been created and this instrument specifies amphetamine as an additional controlled drug to those 16 controlled drugs already covered by the offence and also specifies the limit in blood concentration for amphetamine. Whilst the primary legislation allows for the limit to be specified in urine as well, the limit has only been specified in blood. This is because currently it is not possible to determine with sufficient scientific certainty what the corresponding limit would be for amphetamine (or any drug) in urine.

- **Consolidation**

  This is only the second time that the regulation-making power in section 5A of the 1988 Act has been used. The instrument is therefore amending The Drug Driving (Specified Limits) (England and Wales) Regulations 2014 for the first time and a consolidation is not required.

8. Consultation outcome

8.1 The consultation on the proposed drugs and their limits took place from 9 July to 17 September 2013. The option of taking a zero tolerance approach to 8 illegal drugs and a risk based approach to 8 drugs most associated with medical use was supported. However, as amphetamine is both used illegally and medicinally neither approach was proposed and instead asked for views from consultees. The majority of responses favoured a limit of 50µg/L or lower. A second consultation proposing to include amphetamine and a limit of 50µg/L thus took place from 17 December 2013 to 30 January 2014.

8.2 The Government recognised that there was some concern from specialists in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) on specifying a limit of 50µg/L and made a commitment to reconsider the limit in the light of those concerns and to re-consult at a later date. The Government informally consulted with the medical community, particularly those specialising in the treatment of ADHD based at Kings College London, regarding what amphetamine blood concentration levels would typically result from legitimate medicinal usage and based on that advice has concluded that a limit of 250µg/L as a limit that would not discourage ADHD sufferers from seeking treatment. The Government also consulted with the Secretary of State's Honorary Advisory Panel on Alcohol, Drugs and Substance Misuse regarding the amphetamine blood concentration levels that would typically result from substance misuse. The Advisory Panel, quoted analysis of 2,995 blood samples taken between 2008 and 2012 from across the UK in suspected drug drive cases showing median and average concentrations of amphetamine were 270µg/L and 456µg/L respectively.

8.3 The Government has, therefore, concluded from its consultation with the above ADHD specialists and the Advisory Panel that the level of 250µg/L is one that would successfully balance the legitimate use of amphetamine for medical purposes against its abuse by those who kill and injure on the road as a result of taking amphetamine. In September 2014 the Government indicated that it intended to re-consult on a limit for amphetamine. However, given the extensive discussions that it has held with medical stakeholders it now takes the view that it has had a sufficient opportunity to consider the views of all of the relevant parties and that conducting a third formal consultations on a limit for amphetamine is no longer appropriate or necessary.

9. Guidance

9.1 To support the introduction of the new offence, the Department aims to do the following:

- Raise awareness of the new offence, and the penalties if caught;
- Make drug driving as socially unacceptable as drink driving;
- Raise awareness of the dangers of driving whilst impaired by drugs, deter drivers from driving under the influence of drugs and ultimately reduce casualties;
- Illustrate the action Government is taking to improve road safety;
- Work with communication and policy teams from different government departments so that they are aware of the activity we are undertaking and key messages well in advance;
- Give clear, timely, accurate and consistent advice to stakeholders – including the rationale for the new offence and how it will be enforced.

9.2 A further objective is to ensure that those taking properly prescribed and supplied medicines continue to do so, and are not discouraged from taking their medication or indeed from driving. To this end the Department has liaised with the Medicines and Healthcare products Regulatory Agency ("MHRA"), an agency of the Department of Health. The MHRA has a communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public. The MHRA has identified the medicines that contain controlled drugs which are specified for the purposes of the new offence including amphetamine based medicines and those that will metabolise in the body to amphetamine. They have contacted the manufacturers of these drugs about highlighting in patient information leaflets the importance of taking specified controlled drugs in accordance with medical advice. These amended patient information leaflets have started to accompany the affected medicines.

9.3 We are also working with healthcare professionals to explore other methods of explaining the new offence to patients. We published guidance to healthcare professionals on 3 July 2014 which is available at https://www.gov.uk/government/publications/drug-driving-and-medicine-advice-for-healthcare-professionals. We have also launched the 'Am I Fit to Drive' campaign for pharmacists so that they have the knowledge to support patients when picking up prescriptions from their pharmacist. We will continue to seek opportunities to provide healthcare professionals with further suitable advice to use in discussions with those in their care who are taking medicines containing specified controlled drugs, including amphetamine.

9.4 We have taken steps to ensure that the offence and the effect of the regulations have been fully explained to the police to enable them to provide appropriate guidance to enforcement officers and will be providing guidance to magistrates.

10. Impact

10.1 The impact on business, charities or voluntary bodies for the whole offence with the inclusion of the 17 controlled drugs including amphetamine is £5.74m. This cost is to the pharmaceutical companies to amend the product information for the

medicines that contain the controlled drugs to be specified in the regulations. We do not anticipate any additional cost as manufacturers of amphetamine medicines were included in the assessment as it was always the intention to include amphetamine in the new drug driving offence. This will bring the new drug driving offence to the attention of the prescriber and the patient and how to raise the medical defence.

10.2 The impact on the public sector is through an expected increase in proceedings in the criminal justice system. The Impact Assessment estimates there will be an increase of 8,200 proceedings each year over a 20 year period (2015-2034) leading to costs to the Crown Prosecution Service of £22m and to the criminal justice system of £133.5m and to the police of £136m over a 20 year period. We further estimate the new offence will lead to 31,620 people receiving a community order sentence and 4,400 people will serve a custodial sentence. The costs will be offset by casualty savings where we estimate 84 fewer fatalities, 331 fewer serious injuries and 843 fewer slight casualties over a 20 year period. This will result in estimated casualty savings of around £218m plus income from fines and victim surcharge of £16m over this period, thus providing an estimated overall net cost of £79m over the 20 year period. This impact has been assessed on the basis of 17 controlled drugs including amphetamine being specified for the new offence.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the UK legislation website at www.legislation.gov.uk

11. Regulating small business

11.1 The legislation does not apply to small business. The businesses affected are the large pharmaceutical companies who are amending the product information for the medicines containing specified controlled drugs.

12. Monitoring and review

12.1 The Department will monitor and evaluate the effect of the new section 5A offence. A specification for evaluating the new offence was issued to tenderers in 2013 and a supplier was selected who is currently collecting baseline data.

13. Contact

13.1 Martin Ellis at the Department for Transport, Tel: 020 7944 6945 or e-mail: martin.ellis@dft.gsi.gov.uk can answer any queries regarding the instrument.