



Department
for Transport

Drug Driving - Summary of Responses to the 2 Consultations:

Specifying the drugs and their
corresponding limits for inclusion in
regulations for the new offence of
driving with a specified drug in the body
above a specified limit

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Executive summary

1. The Government set out in the consultation its preferred proposed option (Option 1) to set a 'lowest accidental exposure limit' for 8 controlled drugs most associated with illegal drug use and road safety risk based limits recommended by an Expert Panel¹ for a further 8 controlled drugs.
2. The Government also provided 2 other options to offer a comparison with the preferred approach. Option 2 followed the Expert Panel's recommendations to include 15 controlled drugs in the regulations with corresponding limits all based on a road safety risk approach. The third option, Option 3, proposed a zero tolerance approach (that is, a 'lowest accidental exposure limit') for 16 controlled drugs. The consultation was accompanied by an impact assessment to assist in making that comparison. The consultation ended on 17th September 2013.
3. The Government also proposed to include amphetamine in the new offence, but asked for views on what a suitable limit might be. The Government prioritised the consideration of those views and published a further consultation² on a proposed limit of 50µg/L for amphetamine on 19 December 2013. This time the consultation only covered England and Wales as the Scottish Government informed the UK Government they would carry out their own consultation later in 2014. The consultation on a proposed limit of 50µg/L ended on 30 January 2014. This summary, therefore, includes a consideration of both consultations.
4. A total of 94 responses were received to the main consultation on the 3 possible policy approaches. Not all individuals or organisations provided responses to all questions. The responses were broken down as set out in **Table 1**.

Table 1: Breakdown of responses by type of organisation

Local Authorities & Devolved Administration	4
Police	3
Partnerships and voluntary organisations for road safety	7
Approved Driving Instructors	2
Representatives from medical, toxicology and academic organisations or individual academics	29
Private organisations and members of the public	43
Public bodies	3
Voluntary organisations in the drugs field	3
TOTAL	94

¹ The Expert Panel's report 'Driving under the influence of drugs' is available at <https://www.gov.uk/government/publications/driving-under-the-influence-of-drugs--2>

² <https://www.gov.uk/government/consultations/drug-driving-amphetamine-limit>

5. The consultation took the form of a questionnaire composed of 8 questions. Detailed responses to each of these questions are provided below. The full questions are at **Annex D**.
6. The Department would like to thank all respondents for their contribution. All responses were carefully considered.
7. Of the 94 responses, 4 provided no comment on whether they agreed or disagreed with the Government's proposed Option 1 approach. Of the remaining 90, 43 agreed with Option 1 (48%) and 47 disagreed (52%). Of the 47 who disagreed, only 14 gave a view as to which other policy option they preferred – 11 for Option 2 (12%) and 3 for Option 3 (3%). 33 of the 90 (37%) thus did not give a view on which alternative option to Option 1 they preferred.
8. 28 of those who disagreed with the Government's proposed approach were only concerned with the proposed limit for cannabis and did not offer a view on which alternative approach they preferred. The majority of these were concerned that cannabis users would be detected many days after smoking cannabis. These respondents appear to have misunderstood that the Government has not proposed to specify the metabolites of the drug which persist for a long time, but only the blood concentration of the active constituent THC which is broken down in a matter of hours in all but the heaviest users of cannabis. It is not our intention to detect drivers who may have consumed cannabis accidentally or may have consumed the drug several days prior to driving. If these responses were excluded, then the majority agreed with the Government's preferred approach.
9. The almost 50/50 split in respondents' views in agreeing or disagreeing with the Government's proposed approach demonstrates that this is a difficult issue. It is clear that a zero tolerance approach to all the proposed drugs (Option 3) is not attractive to the vast majority of respondents. However, only 12% confirmed they would prefer a risk based approach to all drugs (Option 2). Some of the 33 respondents who did not give a view might prefer Option 2. However, given that no view was expressed, it is difficult to be sure what this group of respondents would prefer. We can, therefore, only be sure of the following preferences, which excludes the 4 that did not give a view on whether they agreed or disagreed as set out in **Table 2**.

Table 2: Preferences to the Option approaches

Option	Respondents	Percentage
One	43	48%
Two	11	12%
Three	3	3%
No preference	33	37%
Total	90	100%

10. The Government recognises that its preferred approach has divided opinion. However, the consultation demonstrates that on balance there is clearer support for the Government's preferred option than the 2 alternative approaches presented. The Government has thus concluded

that Option 1 is still the best option to proceed with. The Government will take this approach in the forthcoming regulations to be presented to Parliament.

11. There were a number of other questions the Government asked respondents to consider.

Is it possible to specify limits in urine?

12. The Government's scientific advice was that it is not possible to establish evidence-based concentrations of drugs in urine which would indicate that the drug was having an effect on a person's nervous system and wanted to check if respondents agreed. 33 of the 34 who responded to this question agreed with the Government's advice.

Is the approach proposed when specifying a limit for cannabis reasonable for those who are driving and being prescribed with the cannabis based drug Sativex which is used to treat multiple sclerosis?

13. The Government wants to ensure that these patients are not deterred from taking their medication or from driving if they are not impaired to do so. 29 of the 36 who responded to this question agreed that the Government's proposed approach was reasonable.

Are there any other medicines we have not taken account of that may be caught by the zero tolerance approach to 8 of the controlled drugs?

14. The following medicines and conditions although rare were highlighted in **Table 3** as being in a similar position to multiple sclerosis patients taking Sativex.

Table 3: Additional drugs and their conditions requiring special attention

Controlled Drug	Condition
Diamorphine (6-MAM)	Sickle-cell disease Opiate dependent substitute
Ketamine	Neuropathic pain
Selegiline (methylamphetamine and/or amphetamine)	Parkinson's disease

15. We are therefore proposing to take the same approach to these drugs as we propose taking to Sativex to ensure these patient groups are able to continue to drive provided they are not impaired to do so. Although we are not proposing to take a zero tolerance approach to amphetamine, we accept that some conditions such as ADHD and narcolepsy may be affected by the limit of 50µg/L as proposed in the second consultation on amphetamine. This is considered below in the Executive Summary on the amphetamine consultation and in more detail at Chapter 6 pages 34-43.

Does any business believe the proposals will have any impact on them?

16. Only 1 business from the private sector, a pharmaceutical company, stated that there would be an impact upon them in amending the information that accompanies their products. The Department accepted this and used the costs supplied to extrapolate across the

pharmaceutical industry and concluded the costs to the industry were £5.7m. The Department thus submitted a revised Impact Assessment to the Regulatory Policy Committee for their consideration. We will, therefore, include these costs in a revised impact assessment that we will present to Parliament along with the finalised regulations. A further private sector business from the forensic service providers also stated that there is likely to be an impact upon them in developing their analytical standards but acknowledged that any costs would be passed onto the provider.

17. A Summary Analysis of responses to the consultation in a chart form is at **Annex C**. A number of consequential issues were also raised by the respondents and these are addressed in the detailed responses below.

Executive summary of amphetamine consultation

18. The consideration of the original consultation on what a suitable limit for amphetamine is set out in the amphetamine consultation. This summary therefore focuses upon the responses to the proposed 50µg/L limit for amphetamine. The responses were as follows as set out in **Table 4**.

Table 4: Breakdown of responses by type of organisation

Local Authorities & Devolved Administration	1
Police	2
Partnerships and voluntary organisations for road safety	3
Representatives from medical, toxicology and academic organisations or individual academics	5
Private organisations and members of the public	7
TOTAL	18

19. The consultation took the form of a questionnaire composed of 4 questions. Detailed responses to each of these questions are provided below. The full questions are at **Annex D**.
20. The Department would like to thank all respondents for their contribution. All responses were carefully considered. The preferences of the respondents on whether they agreed or not with the proposed 50 limit is set out in **Table 5**.

Table 5: Preferences to the proposed 50µg/L limit for amphetamine

Option	Respondents	Percentage
Agreed	8	44%
Disagreed – too low	4	22%
Disagreed – too high	3	17%
Neither agreed nor disagreed	3	17%
Total	18	100%

21. Whilst overall there is more support for the Government's proposed limit the Government recognises the significant medical concerns. The specialists in ADHD argued that it affects the ability to concentrate and

whilst patients do represent an increased road safety risk when un-medicated, they are just as safe as the general population when taking their medication. As the Government wants to ensure that ADHD patients seek and receive treatment it has decided to re-consider the proposed limit and re-consult at a later date.

22. The Government has every intention to include amphetamines in the regulations but wants to ensure that the limit is appropriate for England and Wales. Once a limit is determined via consultation the Government will specify a limit for amphetamine in regulations at the earliest opportunity. In the meantime, the Government will present the regulations on the other 16 drugs with the proposed limits to Parliament for their consideration in order to get the new offence in place later in 2014 as set out below in **Table 6**.
23. The other 3 questions did not result in any further information that the Government was not already aware of or had already concluded from the main consultation, namely it has agreed to include the cost of amending product information on medicines in the next impact assessment.

Table 6: The final list of drugs and their limits to be included in regulations to present to Parliament:

Drug	Threshold limit in blood
Benzoyllecgonine	50µg/L
Clonazepam	50µg/L
Cocaine	10µg/L
Delta – 9 – Tetrahydrocannabinol (Cannabis & Cannabinol)	2µg/L
Diazepam	550µg/L
Flunitrazepam	300µg/L
Ketamine	20µg/L
Lorazepam	100µg/L
Lysergic Acid Diethylamide (LSD)	1µg/L
Methadone	500µg/L
Methylamphetamine	10µg/L
Methylenedioxymethamphetamine (MDMA – Ecstasy)	10µg/L
6-Monoacetylmorphine (6-MAM – Heroin & Morphine)	5µg/L
Morphine	80µg/L
Oxazepam	300µg/L
Temazepam	1,000µg/L

1. Introduction

- 1.1** The Review of Drink and Drug Driving Law by Sir Peter North, published in June 2010, concluded that there was “a significant drug driving problem” with an estimated 200 drug driving-related deaths a year in Great Britain. However, at the time of the Review in 2010, around 41% of the proceedings in magistrates’ courts for driving whilst impaired through drugs under section 4 of the Road Traffic Act 1988 were withdrawn or dismissed. The comparable figure for exceeding the drink drive limit is just 3%. Those figures have since remained broadly the same.
- 1.2** A new offence of driving over a specified limit (in blood) for specified controlled drugs will reduce the wasted time, expense and effort involved for the police, the Crown Prosecution Service (CPS) and the Courts when prosecutions fail under the existing offence.
- 1.3** That is why in May 2012 the Government included the new offence in a Bill, which is now the Crime and Courts Act 2013³. Section 56 of that Act inserted a new section 5A into the Road Traffic Act 1988. Section 5A(8)(a) includes a regulation-making power, exercisable by the Secretary of State in relation to England and Wales, to specify the controlled drugs to be covered by the new offence and the corresponding limit for each.
- 1.4** The Department for Transport, therefore, launched a public consultation⁴ on 9 July 2013 seeking views on the Government’s proposed drugs and their corresponding limits to be specified in regulations to be laid before Parliament. The consultation was extended to Scotland at the request of the Scottish Government. The second consultation on a proposed limit for amphetamine was restricted to England and Wales and was launched on 19 December.

³ <http://www.legislation.gov.uk/ukpga/2013/22/contents/enacted>

⁴ <https://www.gov.uk/government/consultations/drug-driving-proposed-regulations>

2. Questions 1 & 2

Views on the Government's proposed drugs and their limits including possible alternative approaches

2.1 Responses from Local Authorities and Devolved Administrations (4):

All 4 agreed with the Government's proposals. The Department has included both a response from Transport for London and The Mayor of London's Office under this category. The Welsh Government also fully supported this approach. Buckinghamshire County Council also supported the Government's proposals. The overriding view was that the proposals appear to be a balanced and pragmatic approach.

Agreed: 4 out of 4

2.2 Responses from Police (3):

The National Roads Policing lead responded that they supported the Government's proposed policy option. However, they added that "the current and future procedure which is, to test for alcohol first and if a positive evidential breath test, any drug driving is abandoned in preference for the much cheaper and quicker alcohol breath process. The penalties associated with both alcohol and drug driving are the same."

The Police Liaison Office at the Welsh Government also agreed with the Government's proposed policy option stating that "Option 1 appears to be a balanced approach sends a clear message that illegal drugs and driving are not acceptable.... sets a limit on those controlled, but not illegal drugs and by formal assessment considered the most likely to be misused is a positive initiative". They added, "Some people may be affected by taking a quantity [of medication] within the therapeutic range and should not be driving and in that instance 'impairment' would therefore continue to be assessed on a case by case basis."

Finally, West Yorkshire Police also agreed with the Government's proposals.

Agreed: 3 out of 3

2.3 Responses from Partnerships and Voluntary Organisations for road safety (7):

6 of the 7 stakeholders agreed with the Government's proposed approach. Living Streets added that "the government has to ensure that the medical profession is fully briefed and on-board with reporting to the DVLA medical conditions treated with prescription drugs that may impair driving, and are proactively advising all patients when medication may affect driving and insisting on informing the DVLA". Brake similarly stated that "at present medical professionals are often not delivering on

their duty to advise patients on fitness to drive issues, or reporting patients who will not self-report to the DVLA⁵. This must be addressed to fully tackle the issue of drug driving.” This is addressed along with other communications issues in the Next Steps section on communications at Chapter 10, paragraph 10.2. It is also addressed in Chapter 7, paragraph 7.15 where those conditions that are notifiable condition⁶ and also where a zero tolerance approach is proposed.

The AA stated that whilst they agreed with Option 1 there may be a need for further studies and refinement of regulations as intelligence builds up when prosecutions grow. The Government’s evaluation of the new offence’s operation until February 2016 should provide insight into the effectiveness of the new offence and the Government will consider the case for amending the regulations subsequently if necessary.

The only organisation in this group that did not support the Government’s proposals was RoadPeace who stated “RoadPeace strives to be evidence based and thus, supports that recommended by the Expert Panel appointed by the government to advise on impairment levels. RoadPeace opposes impaired driving as well as the much larger problem of sober unsafe driving. But we are not an anti-drugs charity and do not want to see the priorities of road safety be diverted for this end.”

Agreed: 6 out of 7

2.4 Responses from approved driving Instructors (2):

1 driving instructor agreed with the Government’s proposed approach, stating “we need these drug people off the roads as they pose a daily threat to myself and those I am attempting to teach to drive.” The other stated that whilst he agreed with the Government’s proposals, “I do not believe that there should be any distinction made between medical and recreational use in the context of the proposals.” This suggests that the respondent may prefer option3, the zero tolerance approach. The respondent was also concerned that designer variants of cannabis may not be detected and that a wider range of drugs should be included as “People will purposely seek out drugs which aren’t tested for.”

Agreed: 1 out of 2

2.5 Responses from representatives from medical, toxicology and academic organisations or individual academics (29):

Of the 29 responses from this group, 17 agreed with the Government’s proposed approach (Option 1), whilst 9 disagreed and 3 did not offer a view on whether they agreed or disagreed.

Of the 9 who disagreed with Option 1, 3 stated that they agreed with Option 2 and 2 with Option 3. A further 3 of those that disagreed with Option 1 did not give a view as to which alternative approach they

⁵ Road Safety Research Report No. 91 The Attitudes of Health Professionals to Giving Advice on Fitness to Drive, Department for Transport, 2010

⁶ Medical conditions that must be notified to the DVLA and the process is explained here <https://www.gov.uk/driving-medical-conditions>

preferred and the final respondent of this group said they strongly disagreed with Option 3 and offered no view on Option 2.

Those that agreed with the Government's preferred approach included those set out in **Table 7**:

Table 7: Medical organisations agreeing with Option 1 approach

College of Mental Health Pharmacists	Chronic Pain Policy Coalition
European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)	Faculty of Pain Medicine (Royal College of Anaesthetists)
Pain UK	Pharmacy Voice
ROAR Forensics	Royal College of Psychiatrists in Wales
Royal Pharmaceutical Society	Sheffield Teaching Hospitals NHS Trust
Shingles Support Society	Sickle Cell Society
The British Pain Society	UK Clinical Pharmacy Association

2.6 The overriding view from this group of respondents was that Option 1 offered a balanced and pragmatic approach. Sheffield NHS Teaching Hospital stated “it would be perverse to provide a “legal” blood limit on the use of illegal substances when driving.”

Whilst there was support for the Government's proposed approach, it was often accompanied with a view that there needs to be clear information made available to patients, healthcare professionals and the general public about the new offence. In addition, several respondents argued that patients need to be aware that they must declare to the DVLA if they have a condition that could impair their driving. Some respondents also suggested that it would be useful to provide information on what average doses would equate to in the proposed blood limits. Both these points are addressed in the Next Steps at Chapter 10, paragraph 10.2.

ROAR Forensics also agreed with the overall approach but suggested that LSD was excluded from the regulations because it has not been a major drug of abuse for decades. They also argued that “the pharmacology of LSD means that invariably it is only the metabolites that may be detectable. There are also stability issues around LSD in body fluids that further reduce the chances of detection.” This is discussed in the ‘other issues’ at paragraph 2.10.

ROAR Forensics also thought that the proposed limit of 500µg/L for methadone was too high as the limit was within the range of concentrations observed in fatalities associated with the drug. The Government acknowledges that there may have been instances where road fatalities had been observed where blood concentrations were lower than the proposed limit of 500µg/L. However, there may have been other drugs or alcohol present. Data⁷ provided by the Home Office's Centre

⁷ Page 28 of the Expert Panel report ‘Driving under the influence of drugs.’

for Applied Science and Technology (CAST) to the Expert Panel of blood samples taken by 1 forensic service provider between 2008 and 2012 from drivers involved in road traffic accidents or witnessed impairment showed that 80% of the samples where methadone was present, another drug or alcohol was also present.

The Government, therefore, does not believe the fact that some fatalities had the presence of methadone below the proposed limit justifies lowering the Expert Panel's recommended limit. However, it is recognised that there could be a driver taking a number of drugs, each of which could be below the proposed specified limits for the individual drugs, but in combination could pose a road safety risk. It is unlikely that a person would be below the specified limits if a zero tolerance approach for a number of commonly abused drugs is taken, as proposed. In any event, it would be possible to prosecute such a driver for the current section 4 impairment offence where impairment is present.

ROAR Forensics also stated that clonazepam is predominantly metabolised to 7-aminoclonazepam and this is the usual compound detected in patients prescribed the drug. 7-aminoclonazepam is not listed separately as a controlled drug in the schedule to the Misuse of Drugs Act and therefore cannot be specified in the regulations. Since 7-aminoclonazepam can be specifically and directly related back to clonazepam, specifying clonazepam would be sufficient to detect those taking this particular drug or its metabolite when driving over the specified limit.

The respondents who stated that they preferred Option 2 typically argued that the Government should not take a zero tolerance approach to the 8 illegal drugs because it could lead to prosecution when the driver might not be impaired. This group of respondents therefore argued that the Expert Panel recommended risk-based approach should be taken. Those that disagreed with the Government's proposed approach and favoured Option 2 included:

British Medical Association (BMA)

Independent Scientific Committee on Drugs (ISCD)

The Secretary of State for Transport's Honorary Advisory Panel for Alcohol, Drugs and Substance Misuse in driving

ISCD said that "the success of our risk-based drink-driving law has been attributed to the way that drink-driving became socially and morally unacceptable. A zero-tolerance approach, which penalises people who may not be impaired, is less likely to generate the same 'buy-in' from people, who are unlikely to feel that the law corresponds to a self-evident moral and social norm." The BMA similarly stated that "the risk based stratified approach used with drink driving would be the most effective policy option."

The Secretary of State for Transport's Honorary Advisory Panel for Alcohol, Drugs and Substance Misuse considered that "the Government were conflating two issues; that of impairment to drive when using drugs, which was the reason for the formation of the expert group and the previous concerns, and that of the criminality of illicit drugs."

With regard to the ISCD, the BMA and the Advisory Panels' comments the Government takes the view that there is a difference between alcohol and drugs as the drugs proposed at a 'lowest accidental exposure limit' are in the vast majority of cases obtained illegally, whereas alcohol is typically obtained legally. It is therefore appropriate that a zero tolerance approach should be in place for illegal drugs and a risk based limit is in place for alcohol.

Of those who preferred the Option 3 zero tolerance approach, the majority were toxicologists or forensic service providers. LGC laboratory, for example, stated "Of the drug positive samples tested at LGC between 2008 and 2012 benzodiazepines were the second most prevalent..... These medicinal drugs represent a significant road traffic risk. We believe that there is no need to set the limits for these medicinal drugs at a higher level. Prescribed users will be able to claim the medicinal defence even when the limits are set lower. Lower limits will enable the prosecution of un-prescribed use."

Similarly LGC thought that morphine should be at a zero tolerance level as "the use of morphine, which has a longer half-life, would be a better option as a heroin metabolite. Any driver using morphine under prescription has the medical defence option available."

As set out in the consultation, the Government believes that the costs of investigating the medical defence of patients by additionally taking a zero tolerance approach to medicines outweighs any potential economic benefit. This is why the limits at a road safety risk based approach have been proposed.

Agreed: 17 out of 29 (3 offered no view)

2.7 Responses from private organisations (5) and members of the public (38):

2 of the private organisations were manufacturers of drug screening devices and both agreed with the Government's approach. 2 other private organisations, the Association of British Insurers and Napp Pharmaceuticals also agreed with the approach.

Only Reckitt Benckiser Pharmaceuticals disagreed with the Government's proposed approach preferring the zero tolerance approach (option 3).

Of the 38 responses from members of the public, 4 agreed with the Government's proposed approach and 33 disagreed, with 1 not commenting either way. Of the 33 respondents who disagreed, 5 stated that they preferred Option 2. The remaining 28 only commented upon the proposed cannabis limit, raising concerns that cannabis users could have a blood-drug concentration which was over the limit as much as 24 days after they had smoked the drug, with several pointing to evidence from a US study⁸ which suggests this. However, this study states the evidence refers to chronic cannabis users (i.e. users who had smoked up to 10 joints per day for as long as 10 years). The Expert Panel advice on page 63 of their report 'Driving under the influence of drugs' is that "for

⁸ http://www.aacc.org/publications/clin_chem/podcast/Documents/ClinChem201108_Huestis-OralFluid.pdf

the purposes of drug analysis the window of opportunity for the detection of THC after single dose would be quite narrow and less than 9 to 12 hours.” The Government believes that the wider public would not be comfortable with limits being set in order to ensure that long-term heavy cannabis users would not be detected.

Agreed: 8 out of 43 (1 offered no view)

2.8 Responses from public bodies (3):

The DVLA agreed with Government’s proposed approach as did the Chief Fire Officers Association. The Crown Prosecution Service (CPS) also agreed and said that “We do not consider [Option 2] meets the objective of the new offence. By allowing limits based on road safety risks, we agree that this suggests that low level drug use is acceptable, in conflict with the Misuse of Drugs Act 1971.” The CPS also thought that “from a prosecutorial perspective, an across-the-board zero tolerance approach would present practical problems. The CPS and the Police would in all likelihood be inundated with defences, many of them potentially legitimate. This would have an impact on all Criminal Justice agencies.”

Agreed: 3 out of 3

2.9 Responses from voluntary organisations in the drugs field (3):

All 3 disagreed with the Government’s proposed approach but only 1, a cannabis information website, stated they preferred Option 2. The other 2 organisations, Release and Drug Equality Alliance were concerned that road safety policy was being used to tackle an unrelated social problem. Release stated that “there is currently no offence under the Misuse of Drugs Act 1971 of having a controlled drug in your body. Section 5A in effect creates a strict liability offence of having a specific-limit (potentially set at zero) of a controlled substance in your body when driving or being in control of a motor-vehicle.”

Release also thought that “the cost of implementing these proposals, through the science, the training, the transporting and maintenance of the equipment to a satisfactory level will be prohibitive.” The Government recognises that the costs are greater than for drink driving but does not believe they are prohibitive. Other organisations, including the National Roads Policing lead and the CPS who will need to bear some of the costs did not state in their consultation response that the costs would be prohibitive. The increase in costs relative to drink driving is not a reason to abandon the task of having more effective legislation in combating the menace of drug drivers.

Release were also concerned that some research showed that passive inhalation of cannabis smoke has resulted in a plasma THC level of 1-7µg/L. This, they believe, could mean that an individual who has been exposed to passive cannabis smoke, could potentially be over the proposed limit of 2µg/L for THC.

Concentrations of THC in plasma are not the same as those in whole blood, the matrix in which the Government is proposing limits. Plasma THC concentrations equate to approximately double of the

concentrations in whole blood for THC. Our scientific advice is that it is at blood-drug concentrations of 2µg/L that cannabis has an effect on a naïve user. The Government is confident that the scientific advice it has been provided by an expert advisory group⁹, recommending a limit of 2µg/L is at a limit where anything above is unlikely to be through accidental exposure.

Agreed: 0 out of 3

2.10 Other issues

Inclusion of other drugs

A number of respondents expressed concern that some drugs, particularly so called ‘legal highs’ or New Psychoactive Substances (NPS), have not been included in the proposals. The drugs mentioned are included in **Table 8** where their status has been added:

Table 8: Additional drugs proposed by respondents to include in the regulations and their status on whether they are a NPS or controlled under the Misuse of Drugs Act 1971.

Drug	Status
Alprazolam	Class C
Anti-epileptics	Numerous – some are controlled
Antihistamines	Numerous – some are controlled
Buprenorphine	Class C
Dihydrocodeine	Class B
Fentanyl	Class A
Gabapentin	Not controlled but a prescription only medicine
Magic Mushrooms (Psilocybin)	Class A
Mephedrone	Class B
Methoxetamine	Class B
Oxycodone	Class A
Phenazepam	Class C (previously advertised as a ‘legal high’)
Synthetic Cannabinoids	NPS, though some are Class B as depends on the chemical structure
Tricyclic anti-depressants	Numerous – some are controlled

It will not be possible to include these drugs in our current proposed regulations. As 1 screening manufacturer responded, “Please get the ball rolling and sort the others out at a later date. Do not wait for everything. There will be other drugs and medicines that are added to the discussion and the project will not get started.” The Government entirely agrees with this view. The Expert Panel recommended the drugs that are most evident in drug driving after extensively reviewing the evidence. The

⁹ An Expert Advisory Group has advised the Government on the ‘accidental exposure limits’. The group is made up of 4 members of the Expert Panel as well as toxicologists. Their report will be published shortly.

Government believes that it is right to proceed with the evidence as it currently exists and monitor the new offence as we intend to do.

The Department will continue to gather and review evidence on which drugs are found in the driving population, so that this can be reflected in future revisions to the regulations. The Department has also agreed with HM Courts and Tribunal Service that they will record the drugs, which drivers have taken and the quantities found so that we will be able to see what is being found in practice. The Department has also appointed a research company to evaluate the offence. This will include monitoring a range of relevant data to see which drugs are contributing to fatalities and the extent of those not covered by the regulations as recommended by the Expert Panel¹⁰. The Government will consider the case for amending the regulations subsequently if the evidence justifies inclusion of other drugs.

A number of respondents commented on so called 'legal highs'. The Independent Scientific Committee on Drugs (ISCD) argued that the proposed limits contradict the Government's response to the harm caused by NPS, which has been to promote the message that "just because a drug is legal does not mean it is safe". They argued that Option 1 implies that driving with 1 of the 8 illicit drugs in the body is more serious than driving with any other so called 'legal high' in the body. They argue this approach is confusing and dangerous.

In addition, a local authority pointed out that "We have seen in prison establishments that mandatory testing regimes have pushed offenders into switching their substance misuse to Legal Highs to avoid detection, it would stand to reason that the same scenario may occur due to the proposed regulations." The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) similarly pointed to recent research in Germany and the USA, which showed that one of the most cited motivations by young people for consuming synthetic cannabinoids was to avoid detection in drug tests.

However, the Secretary of State's Honorary Advisory Panel on Alcohol, Drug and Substance Misuse suggested the proposed approach could "lead young people to switch to recreational drugs with shorter half-lives, as has happened in the prison populations when zero tolerance for soft drugs was introduced. Most worrying of all, it will be a boost to the market in designer drugs." They also had "significant concerns about a range of wider adverse consequences, not least the incentive it gives for young people to take unknown new substances with unknown potential for severe toxicity in the future."

The Government takes the view that a large number (c.80%) of substances marketed as NPS, including the synthetic cannabinoids that are seen at EU level are already controlled under the Misuse of Drugs Act 1971. The forensic and toxicology laboratories in the United Kingdom are well equipped to test for a range of these substances. In addition, data from the Forensic Early Warning System (FEWS) project has shown that even though substances are advertised as 'legal' they can often

¹⁰ Page 170 of the Expert Panel report '*Driving under the influence of drugs*'.

contain controlled drugs, some of which may be included in these proposals.

Together with the Advisory Council on the Misuse of Drugs (ACMD), the Home Office continues to monitor closely the emerging NPS and trends in the so called 'legal high' market through the UK and EU early warning systems. The Home Office can also ask for advice from the ACMD who can assess whether a substance is a sufficiently harmful drug to warrant control as a temporary class drug under Section 2A of the Misuse of Drugs Act 1971. The ACMD can then undertake a full assessment of the substance for consideration for its permanent control under the 1971 Act.

The Government's drug awareness service, FRANK (www.talktofrank.com), continues to be updated with the latest evidence so that people are aware of the harms of both controlled drugs and the risks associated with uncontrolled NPS.

If evidence emerges during the evaluation of the new offence that drug drivers are switching to any other drug not specified in the current proposals, then the Government can revisit the regulations. However, the Government recognises that NPS would have to be first brought under permanent control under the 1971 Misuse of Drugs Act if this had not already been done. In the meantime, if a person is driving after taking a so called 'legal high' and they do not have a blood-drug concentration in excess of 1 of the specified limits, it would be possible to prosecute the driver for the current section 4 impairment offence if there was evidence of impairment.

Exclude LSD?

ROAR Forensics suggested that LSD was excluded from the regulations as it has not been a major drug of abuse for decades and is difficult to detect. A drug screening manufacturer also stated that as a supplier of screening devices across the world they had never been asked to produce a device which could screen for LSD. The ISCD also stated "the Expert Panel notes that there is scant evidence that it is a significant cause of traffic accidents in the UK proportionate to use." In contrast, the Institute of Advanced Motorists, RoSPA and the Mayor of London Office for Policing and Crime (MOPAC) explicitly supported the inclusion of LSD as it has no recognised medical use.

The Government recognises that if there is not much evidence of LSD being found in drug driving cases then there is a question of whether to include it. On balance the Government consider that even if there are just a small number of cases then it is worth including as the police would have the powers to progress with these cases. However, we also recognise it would be unviable to ask manufacturers to undertake research and development for screening devices to detect LSD when there is unlikely to be a viable market. If a drug driving suspect is arrested on suspicion of driving whilst impaired and the blood sample reveals a positive LSD result above the specified limit then the police will have the option to charge the driver under the new offence. The Government has therefore decided to include LSD in the forthcoming regulations.

Time limit to take blood

A drug screener manufacturer and a road safety charity also recommended that a time limit be set for blood to be taken because some drugs can be metabolised quickly by the body. The Government will work with the police on procedures for the new offence and will emphasise the need to take blood as quickly as possible. However, we believe it would be overly burdensome to require blood to be taken within a given timeframe.

Changes to the enforcement procedures for drink and drug driving, which the Government consulted upon in 2012, are planned to be taken forward in the Deregulation Bill later this year. These changes include allowing registered healthcare professionals to decide whether a suspected drug driver's condition is due to a drug. At present only doctors are permitted to do this. Procedures will also be streamlined for testing drug impaired drivers in hospitals so that a wider range of registered healthcare professionals are allowed to take evidential blood samples. Both of these provisions will speed up the process to take an evidential blood sample. It is expected that these provisions will come into force in early 2015.

Police targeting ethnic groups

A number of respondents had concerns that young black men are likely to be targeted by this new offence. Release, for example, stated "young, black men will be targeted by the police in relation to this new power. In relation to the policing of drug offences this group is 6.3 times more likely to be stopped and searched for a drugs offence than their white counterparts¹¹, despite drug use being lower amongst the black community."

This concern will relate in particular to the use of screeners at the roadside. The police do not have the power to randomly test drivers for either drugs or alcohol. An officer may only administer a preliminary drug test if the officer suspects that a driver has a drug in his body or is under the influence of some drug, if the driver has committed a moving traffic offence, or if the driver has been involved in a road traffic accident

Further, it is both the Government's expectation and the National Roads Policing lead expectation that the police will almost always test for alcohol first at the roadside as it is easier and coincidentally cheaper to do so. The DfT has some limited data on the ethnicity of drivers asked to provide breath alcohol screening tests, as well as the reasons for and results of those tests. Analysis of this data suggests that where a test was requested for the reason "suspicion of alcohol", there was not a large difference in the pass / failure rates across different ethnic groups. Whilst this data is limited, it does suggest that once tested different ethnic groups are just as likely or unlikely to be detected for drink driving. However, the Department will collect evidence on the ethnicity of those tested on suspicion of drug driving as part of the evaluation that is being carried out.

¹¹ Eastwood, N, Shiner, M & Bear, D, 2013, 'The Numbers in Black and White: Ethnic Disparities in the Policing and Prosecution of Drug Offences in England and Wales, Release, United Kingdom

Patients over limits have an increased risk of claims if involved in an accident?

A number of respondents raised a concern that if a patient who was not impaired but was over the specified limit for a controlled drug which they had been prescribed and had taken in accordance with medical advice, and was involved in an accident, could be at risk of losing insurance claims against other drivers. The reason for this is the fact that the patient was over the specified limit for the drug might be taken to mean they were impaired and therefore wholly or partially responsible for the accident, even though they were not impaired and were entitled to rely on the medical defence in criminal law. This risk, it was suggested, increases for those taking the small number of medications which attract the proposed zero tolerance approach. 1 patient group, the Sickle Cell Society said that they were aware of a case where a patient had been advised to withdraw a claim in these circumstances.

The relationship between an insured party and their insurance company is contractual. Any medical condition (along with any medication taken) should be disclosed by the insured party to the insurer and the contract of insurance should be entered into on the basis of those facts. Provided the insured party is taking their medication in accordance with medical advice and that the insurance provider is aware of that fact, an insurance provider would not be able to avoid its contractual obligations where both the condition and medication has been disclosed and there has been no breach of the terms of the insurance contract. The existence of this new drug driving offence does not impact upon the above contractual relationship.

In addition, by creating the medical defence, Parliament has seen fit to specifically identify a group of people who may have a blood concentration level that is above the statutory limit but whose ability to drive may not be impaired by virtue of that fact. In order to establish liability in a negligence case, the other party would have to demonstrate that the person driving on medication had acted negligently towards them and suffered harm as a result. The driver on medication, however, has done everything required of them to comply with the requirements of a closely defined statutory exemption and their conduct in this regard has been completely lawful. In the absence of further evidence to the contrary, the Government believes that it is extremely unlikely that a court would find that the driver taking medication has breached their duty of care to other road users.

Testing of blood samples

LGC laboratory pointed out that the analysis for drugs (and metabolites) in biological fluid is not as standardised as it is for alcohol due to the many factors involved. The quality of alcohol measurements is significantly better as there are Certified Reference Materials (CRMs) available to demonstrate accuracy and to give lower measurement uncertainty. The Government recognises these issues and is currently working with toxicology providers to understand the extent of any analytical variations and develop guidance to ensure any potential impacts are minimised.

A related issue raised by ROAR Forensics was that “in order to cover the proposed drugs and provide a quantitative result (notably in poly drug misusers, which is common in the UK) there will be a requirement to obtain more blood than current practice. Approximately 10ml of blood could be required compared to the current 5ml sample. To ensure that there is sufficient sample to permit the analytical requirement there would have to be a minimum volume, notably as at present it is not uncommon to receive far less than 5ml. There is then the issue of ensuring that there is a similar volume available for the defendant's sample (assuming that, as now, a divided aliquot is provided to the defendant) and that there are laboratories available for the defence to use for the testing. There are relatively few that offer this service now.”

The Government is considering changing legislation to allow the use of vacutainers, which are more commonly used in the health sector and would allow blood kits to be used to collect more blood. In the meantime the Government's expert advice is that 5ml vials will be sufficient provided 5ml of blood is collected. The Government also recognises that whatever volume of blood is obtained, it must be divided equally between the defendant and the prosecution. We recognise that advice needs to be provided to defendants to ensure their sample is stored correctly and are advised on which laboratories are available to send their sample for analysis. The Department will therefore be updating the advice that police issue when providing the sample to the defendant.

'Off-Label' use

An NHS Foundation Trust said that “within palliative care there is a lack of large randomised controlled trial evidence... This lack of evidence often manifests itself in medicines being used “off-label” or “off-license.” In practise this means that medicines are often used in excess of the recommended (British National Formulary) maximum. Many of these patients are able to continue with “normal” activities of daily life, including driving, while taking these large doses of medicines. Our concern is that these “off-label” or “off-license” (large) doses may mean that our patient group would have a higher than threshold limit in the blood and yet be safe to drive.”

Their concern is that patients who had been prescribed off-label doses of medicines would be prevented or deterred from driving because they might not be able to provide evidence they had taken the medication in line with the advice of a healthcare professional.

There may, therefore, be a need for medical staff to produce additional written information if they believe that patients are using the medication “off-license” or when patients are titrating up (i.e. process of increasing their doses) so that they are clear on the healthcare professional's instructions and associated warning not to drive during a period of titration. The respondent thought that this information might need to be provided in a written format and not just verbally in case it was required for the medical defence. This is addressed in 'Next Steps' at Chapter 10, paragraph 10.2.

Lower limits when in combination with alcohol

A small number of respondents asked why no limits were proposed where drugs were taken in combination with alcohol, as the Expert Panel had recommended.

A limit for drugs and alcohol in combination would require further primary legislation. The Government has no immediate plans to proceed with this. If limits for drugs and alcohol were to be set when combined, it could be technically difficult for the police to implement and for manufacturers to produce different station and mobile screeners, particularly given that this is a new offence. Further, our proposed zero tolerance approach to 8 drugs means that no limit for those drugs when combined with alcohol would be required.

There is already a power for a court to consider whether the existence of alcohol below the specified limit or the presence of a drug where it impaired the offender is an aggravating factor when sentencing for causing death by dangerous or careless driving and thus have the power to increase the sentence.

The Government therefore takes the view that it is more prudent to establish the new offence and evaluate its implementation and re-visit the options if necessary.

A related issue was raised by Transport for London (TfL) who believed that the presence of both alcohol and drugs should be tested, even if a positive alcohol result is obtained first in order to ensure that an accurate, intelligence based, picture of the scale of the drug-driving problem is developed, especially considering the lack of existing data in this area. The Government recognises the dilemma for the Police in wanting to use their resources effectively whilst at the same time having a better understanding of the scale of dual alcohol and drug use. The Government takes the view that it is a matter for each Chief Constable to balance their priorities. The evaluation of the new offence will also seek to understand the extent of drug driving and the research organisation will be working closely with a number of police forces.

2.11 Summary

As set out in the Executive Summary of the 94 responses, 4 provided no comment on whether they agreed or disagreed on the Government's proposed approach. Of the remaining 90, 43 agreed with Option 1 (48%) and 47 disagreed (52%). Of the 47 who disagreed, only 14 gave a view as to which other policy option they preferred as set out in **Table 9**.

Table 9: Preferences to the Option approaches

Option	Respondents	Percentage
One	43	48%
Two	11	12%
Three	3	3%
No preference	33	37%
Total	90	100%

In total 28 of those who disagreed with the Government's proposed approach were only concerned with the proposed limit for cannabis and

did not offer a view on which alternative approach they preferred. As discussed earlier, the majority of these were concerned that cannabis users would be detected many days after smoking cannabis. These respondents appear to have misunderstood that the Government has not proposed to specify the metabolites of the drug which persist for a long time, but only the blood concentration of the active constituent THC which is broken down in a matter of hours in all but the heaviest users of cannabis. It is not our intention to detect drivers who may have consumed cannabis accidentally or may have consumed the drug several days prior to driving. If these responses were excluded, then the majority agreed with the Government's preferred approach.

The almost 50/50 split in respondents' views demonstrates that this is a difficult issue. It is clear that a zero tolerance approach to all the proposed drugs (Option 3) is not attractive to the vast majority of respondents. However, only 12% confirmed they would prefer a risk based approach to all drugs (Option 2). Some of the 33 respondents who did not give a view might prefer Option 2. However, given that no view was expressed, it is difficult to be sure what this group of respondents would prefer.

The Government recognises that its preferred approach has divided opinion. However, the consultation demonstrates that on balance there is clearer support for the Government's preferred option than the other 2 alternative approaches presented. The Government has thus concluded that Option 1 is still the best option to proceed with. The Government will take this approach in the forthcoming regulations to be presented to Parliament.

The Government also believes we have addressed the other issues respondents have raised.

3. Question 3

Views on if agree with the Government that it is not possible to establish evidence-based concentrations of drugs in urine which would indicate that the drug was having a positive effect on a person's nervous system and thus not currently possible to propose specified limits in urine

3.1 Responses from Local Authorities and Devolved Administration (4):

Both Buckinghamshire County Council and the Welsh Government agreed with the view that it was not possible to specify limits in urine. TfL and MOPAC did not offer a view.

3.2 Responses from Police (3):

West Yorkshire Police agreed with not setting limits in urine. The Police Liaison Office at the Welsh Government stated that they were not in a position to comment on the validity of evidence based concentrations of a drug in urine. The National Roads Policing lead understood why it might not be possible to set a specific level in urine for the new offence. However, both the National Roads Policing lead and the Police Liaison Office at the Welsh Government said that an alternative to blood would be required to enable the police to obtain an evidential sample from drivers who could not provide blood. Both organisations have asked that research continues into alternative matrices such as oral fluid and that a second matrix is specified as soon as possible with similar limits to allow its use as an alternative to blood.

The Government recognises the need to address this issue. The Department is, therefore, developing a specification for research into evidential alternatives to blood and potential limits.

3.3 Responses from Partnerships and Voluntary Organisations for road safety (7):

4 respondents agreed with the view that it was not possible to specify limits in urine whilst the other 3 did not comment on whether it was possible or not. However, a Road Safety Partnership also suggested that a positive urine sample, "could be sufficient for a mandatory attendance at a drug service. If an individual tested positive in urine in the same manner as a Drug Testing on Arrest process this could then lead on to a Required Assessment, Conditional Caution or a Restriction on Bail, all of which require engagement with a drug service in their local community." This is not possible under current legislation as the Police and Criminal Evidence Act 1984 only allows drug testing of offenders if arrested or

charged with certain 'trigger' offences linked to drug taking behaviour and under the Drugs Act 2005 this only applies to Class A drugs.

Drug drivers under the new offence are arrested and taken to police stations under section 6D of the Road Traffic Act 1988 in order to obtain a sample under section 7 of the Act with the officer being 'in the course of an investigation' into the drug driving offence(s). They are therefore not charged – not until a positive result from an evidential sample is reported by the laboratory. They could therefore only be asked to provide a further evidential sample once charged, which could be several weeks later (i.e. after the laboratory result has been provided). The result of the second sample would also not be directly attributable to the original incident. It would require primary legislation to amend this to allow the police to use the first sample when arrested for an investigation into drug driving offences rather than when charged.

The Drug Driving (Assessment of Drug Misuse) Bill is currently before Parliament. It was introduced by Graham Evans MP as a Private Members Bill, but did not get voted on at its 2nd Reading in October 2013 and was adjourned to 28 February 2014 but did not have time to be read. The Bill seeks to extend the power to require a person to attend a drug assessment for drug drivers on Class A drugs by amending the Drugs Act 2005. The Home Office is also looking at other ways drug drivers charged with driving with Class A drugs can be encouraged to go for an assessment.

The Government therefore believes that getting drug drivers on to a Required Assessment is preferable and the use of a positive urine sample is a good idea. We will see how the Home Office measures and the 'Assessment of Drug Misuse' Bill progress and consider if any further action from Government is required.

3.4 Responses from approved driving Instructors (2):

One driving instructor agreed that it was not possible to specify limits in urine whilst the other did not offer a view.

3.5 Responses from representatives from medical, toxicology and academic organisations and individual academics (29):

16 of the 29 respondents agreed that it was not possible to specify limits in urine whilst 13 offered no comment. A forensic laboratory suggested that urine levels for workplace drug testing could be set. However, the scientific advice from the Expert Panel¹² is that urine samples can only "provide retrospective information about past drug use rather than provide information about the current effect of the drug on a person." Limits in urine would, therefore, not be able to be set to correspond with risk based limits in blood.

3.6 Responses from private organisations (5) and members of the public (38):

Only 1 member of the public offered a view on this question and that was to agree that it was not possible to specify limits in urine. Of the private organisations, 3 of the 5 also agreed that urine limits could not be set,

¹² Page 56 of the Expert Panel report '*Driving under the influence of drugs*'.

with 1 other not commenting on this question at all. Reckitt Benckiser Pharmaceuticals suggested contacting the National Addiction Centre at Kings' College Hospital to see whether they had any evidence of setting limits in urine is possible. The Department believes this is not necessary as we have already been taking the advice from experts at Kings College and the evidence from the responses was overwhelmingly in agreement that it is not possible to specify evidential risk based limits in urine.

3.7 Responses from public bodies (3):

Both the DVLA and the Chief Fire Officers Association agreed with our scientific advice that it was not possible to specify limits in urine. The CPS accepted the scientific advice, but expressed similar concerns to those raised by the National Roads Policing lead and the Police Liaison Office at the Welsh Government around the need for an alternative to blood testing.

If a medical reason for not giving blood was raised, the CPS has suggested that there needs to be a robust investigation into the claim in order to prevent wide-ranging challenges. The process could involve a formal police interview under caution with the suspect and such considerations should be suggested on police forms dealing with the procedure. The Government will thus work with the police suggesting that they conduct a thorough investigation of anyone claiming a medical reason as to why they cannot provide a blood sample.

In addition, the CPS noted that the lack of an alternative to a blood sample was likely to increase the number of prosecutions and trials for the offence of failing to provide a specimen under section 7(6) of the Road Traffic Act 1988. This could have resource implications for the CPS, the courts and police. The CPS believe the courts, therefore, need to be rigorous in applying established case law about the need for any claims of a medical reason why a person cannot provide a blood sample to be medically recognised and supported by formal medical evidence. The CPS suggest that this should be included in any training for magistrates on the new offence.

As cases of medical reasons why blood cannot be given are currently quite rare we do not expect the number of cases to significantly increase. The Department will monitor cases and if this issue needs to be addressed, we will work with the Justices' Clerks Society to provide guidance to the Justices' Clerks and Legal Advisers who advise magistrates. We will also seek advice on the training of magistrates in this area through the Judicial College as a priority.

3.8 Responses from voluntary organisations in the drugs field (3):

None of these organisations offered a view on this question.

3.9 Summary

Of the 34 respondents who offered a view on the question of whether it is possible to specify limits in urine, 33 agreed with the Government's scientific advice that it was not possible to do so. However, 3 of those that agreed had concerns about the impact of a lack of an alternative to blood on prosecutions. 1 respondent suggested that it might be possible

to specify limits in urine as is done for work place drug testing regimes. However this cannot be specified for risk based limits.

In conclusion, where a view was given, 33 out of 34 agreed with the Government's view.

The Government will take forward the National Roads Policing lead's request to continue research into whether an alternative to blood could be specified in the future. We will also work with the police to suggest they robustly investigate any person claiming a medical reason why they cannot provide blood.

4. Question 4

Is the approach the Government is proposing to take when specifying a limit for cannabis reasonable for those who are driving and being prescribed with the cannabis based drug Sativex, which is used to treat multiple sclerosis?

4.1 Responses from Local Authorities and Devolved Administration (4):

MOPAC and the Welsh Government agreed that this was a reasonable approach given that it will affect such low numbers and that a statutory medical defence was available. TfL did not offer a view on this question, whilst the remaining local authority thought the proposals appeared to be reasonable, but said that it was not scientifically qualified to respond to this question.

4.2 Responses from the Police (3):

The Police Liaison Office at the Welsh Government, the National Roads Policing lead and West Yorkshire Police all agreed this was a reasonable approach. Overall the police view was typified by the National Roads Policing lead who stated “Drivers who are not impaired will need to evidence their prescribed use if a preliminary test is positive. The police will take all reasonable steps to avoid inconvenience to any prescribed users but are aware of the possibilities of fraudulent claims by others and the need to police all such claims.”

4.3 Responses from Partnerships and Voluntary Organisations for road safety (7):

5 of the 7 organisations agreed that the Government’s proposed approach was reasonable with 1 not offering a view and a road safety partnership disagreeing. A typical view of those who agreed was offered by Brake who stated that “if the Government were not to take this approach, and set the limit above the prescription limit of Sativex, the new drug drive law would be undermined and not taken seriously by the public. Drivers who use Sativex are very rare, but cannabis use and driving is widespread and lethal. Therefore on balance, setting a zero tolerance limit is fair and proportionate.”

The road safety partnership that disagreed with the proposed approach suggested that if the dose prescribed exceeds the drug driving level then the prescribers of Sativex should inform the patient that they cannot drive whilst taking this medication. There would then be patient choice as to whether to continue this form of treatment and thus remove the potential impact on the patient and members of the public if they were to be

involved in an incident whilst driving. The Government does not agree with this view. If a healthcare professional considers that a patient taking Sativex can be fit to drive, it would be unfair to prohibit them from doing so. It is clear that the majority of road safety organisations agree with our proposed approach.

4.4 Response from approved driving instructors (2):

1 respondent did not offer a view whilst the other disagreed with our approach as in their view a Sativex user should be considered in the same way as a cannabis user, i.e. a zero tolerance approach. As set out above, the Government believes that it is possible to distinguish between these 2 groups.

4.5 Responses from representatives from medical, toxicology and academic organisations and individual academics (29):

12 of these organisations agreed with the Government's proposed approach to Sativex. The British Medical Association took the view that drivers prescribed with cannabinoid medications should be exempt from the new offence and that prescribers should counsel their patients on the impact of their driving. The Honorary Advisory Panel on Alcohol, Drugs and Substance Misuse also agreed with the approach in dealing with Sativex users, but reiterated their view that the cannabis limit should be set at a risk based level as recommended by the Expert Panel.

The Independent Scientific Committee on Drugs (ISCD) disagreed with the Government's approach and argued that the Government's view as to why a zero tolerance approach to medicinal drugs should not be taken applies equally to cannabis and Sativex. ISCD went on to say that the "Government's approach was likely to cause unintended harm by preventing some patients receiving treatment that minimises their symptoms, and also a nuisance to those who persist with Sativex. There was increased acceptance and utilisation of cannabis-based medicines, with benefits to NHS patients and the Government's proposed approach may stifle their development. "

One doctor argued in a similar vein that "the lack of widespread availability of Sativex leads to many patients having to break the law to obtain illegal cannabis to control their symptoms. As a clinician I am often asked my opinion on this from patients seeking information on the safest way to use it. Commonly they are patients who cannot tolerate opioids or Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) and for whom the few other options are ineffective. So many patients are prepared to break the law in order to achieve some symptom control, which the NHS can't or won't."

14 organisations did not offer a view on this question. For the 15 that did offer a view, 10 were in favour of the Government's approach in its entirety and a further 2 broadly agreed and 3 did not agree.

4.6 Response from private organisations (5) and members of the public (38):

35 out of the 38 members of the public did not offer a view on this question. 2 thought that it was wrong to have a two-tier system, i.e. a

different approach to Sativex users. The final member of the public who offered a view was an MS sufferer who takes Sativex and was in agreement with the Government's approach.

Of the 5 private organisations 2 agreed that the Government's proposed approach was reasonable and the other 3 did not offer a view.

4.7 Responses from public bodies (3):

Both the DVLA and the CPS agreed that the Government's proposed approach was reasonable. So did the Chief Fire Officers Association but they suggested that a further option might be that patients using Sativex for MS could have some form of formal identification system in place, which could be authorised by their GP directly to the DVLA so that records could be immediately flagged or checked if stopped by the police. The Government has considered the viability of a similar system but encountered concerns about data protection, costs, fraud and ensuring that accurate data is maintained as patients move between different types of medication. The Government takes the view that it is in the interests of the patient to allow them to take responsibility for the information they wish to disclose and when. However, it is advisable for patients to keep some evidence of Sativex use with them when driving.

4.8 Responses from voluntary organisations in the drugs field (3):

2 of the 3 organisations did not offer a view on this question. The third did not agree as they took the view that road safety risk based limits should be set for cannabis and thus the situation for Sativex users would not arise.

4.9 Summary

In conclusion, of the 36 respondents that offered a view on this 29 agreed with the Government's approach.

5. Question 5

What a suitable limit for amphetamine might be?

5.1 Responses from Local Authorities and Devolved Administration (4):

Only the Welsh Government offered a view on suggesting a suitable limit for amphetamine and that was to specify it at 50µg/L in line with a number of other European countries.

5.2 Responses from the Police (3):

The Police Liaison Office at the Welsh Government did not offer a view on a suitable limit for amphetamine whilst the National Roads Policing lead suggested a limit of 100µg/L. West Yorkshire Police suggested a zero tolerance approach given the extent of illegal use. The 2 police views were therefore collectively somewhere between a zero tolerance approach and 100µg/L.

5.3 Responses from Partnerships and Voluntary Organisations for road safety (7):

2 of the organisations did not offer a view on a limit, whilst the Institute of Advanced Motorists and RoSPA suggested the Government take the advice of the Expert Panel and set a limit at 600µg/L. By contrast, both Brake and Living Streets suggested a zero tolerance approach. The road safety partnership suggested a limit that was towards the lower end. 3 of the 5 were therefore more inclined to go towards a much lower limit. A typical view was that a similar approach could be taken as with Sativex if a zero tolerance approach was taken.

5.4 Responses from approved driving instructors (2):

Only 1 driving instructor offered a view and suggested that amphetamine should be treated in the same way whether used recreationally or medically, i.e. a zero tolerance approach. This was in line with their preference for a zero tolerance approach to all the drugs.

5.5 Responses from representatives of medical and academic organisations and individual academics (29):

Only 9 of the 29 offered a view on a suitable limit for amphetamine. 2 of the responses stated that there should be a limit that was not a zero tolerance approach but did not suggest a suitable limit. Another respondent also did not propose a limit but thought that the Government should also recognise narcolepsy as a condition for which amphetamine is sometimes prescribed when proposing limits for amphetamine. 1 proposed that the Expert Panel's recommended limit of 600µg/L should be specified whilst another suggested 300 µg/L. A further respondent suggested 100µg/L because whilst recreational use may be less than this only chronic users would be caught by the new offence.

A toxicologist suggested the Government should “pick a level that was equivalent to the European Workplace Drug Testing Society’s cut-off for amphetamine in saliva.” Attempting to determine a blood limit from this saliva limit would result in an approach which was close to a zero tolerance approach. The final 2 respondents suggested a limit of 50µg/L in line with a number of other European countries, although one of these suggested an accumulative approach to all amphetamine type drugs (i.e. adding all the limits together). This would actually result in a much tougher approach as the total limit would be 50µg/L.

This means that of the 6 respondents that proposed a limit, 1 recommended the Expert Panel’s limit of 600µg/L, 4 recommended a limit that was 100µg/L or less, with the other respondent recommending a limit of 300µg/L.

5.6 Response from private organisations (5) and members of the public (38):

Only 1 member of the public offered a view but did not propose a limit but suggested continuing with the police conducting Field Impairment Tests and exclude amphetamine from the new legislation.

Only 1 of the private organisations offered a view, suggesting a limit from 25µg/L to 50µg/L in line with a number of other European countries.

5.7 Responses from public bodies (3):

The CPS did not offer a view on a suitable limit whilst the DVLA suggested accepting the Expert Panel’s recommended limit of 600µg/L. In contrast the Chief Fire Officers Association proposed taking a zero tolerance approach.

5.8 Responses from voluntary organisations in the drugs field (3):

None of these organisations offered a view on a suitable limit for amphetamine.

5.9 Summary

In conclusion, of the 18 that offered a view on a limit for amphetamine 4 proposed 600µg/L, 1 proposed 300µg/L and 2 proposed 100µg/L. 6 proposed a zero tolerance approach whilst 5 proposed a limit of 50µg/L in line with a number of other European countries. There is clear evidence that respondents favoured a much lower limit than the Expert Panel’s recommended limit of 600µg/L, suggesting a limit towards the lower end, i.e. between zero tolerance and 100µg/L. A limit of 50µg/L or less is most acceptable to the respondents in the consultation.

The Government therefore concluded that a limit of 50µg/L limit should be proposed and consulted on this limit from 19 December 2013 to 30 January 2014.

6. A consultation on a proposed limit for amphetamine

Question 5a: Do you agree with the Government's proposed limit of 50µg/L for amphetamine?

6.1 Responses from Local Authorities and Devolved Administration (1):

There was only response from this group and that was from the Welsh Government, who agreed with the Government's proposal, which corresponded to the limit they proposed in response to the earlier consultation.

Agreed: 1 out of 1

6.2 Responses from the Police (2):

The Metropolitan Police and Surrey Police both agreed with the proposed limit. The Metropolitan Police stated "The closer the limit is to a zero tolerance the better the chance of educating drivers that driving under the influence of drugs is a bad idea. There needs to be a clear message that the unlawful use of amphetamine will make a person unfit to drive and that they will be over the limit."

Agreed: 2 out of 2

6.3 Responses from Partnerships and Voluntary Organisations for road safety (3):

RoSPA and Brake supported the proposed limit with Brake adding "Brake strongly welcomes the Government's work to toughen up laws on drug driving, which is desperately needed. It supports the proposals outlined in this consultation, which Brake hopes will send out a clear message that drug driving on amphetamines will not be tolerated."

The South Yorkshire Safer Roads Partnership also agreed with the proposal stating that "The proposed limit of 50µg/L would seem reasonable given the balance of arguments set out in the consultation document. It is recognised that a relatively small number of people who are being prescribed amphetamine are likely to be driving and, in the event of them being stopped, they have the medical defence open to them to use." They also hoped to see mobile screening devices that can test for amphetamine would be available at the earliest opportunity.

Agreed: 3 out of 3

6.4 Responses from representatives from medical, toxicology and academic organisations and individual academics (4):

One individual academic agreed with the proposed limit stating “It is clear that the number of legitimate users of amphetamine for medicinal use above driving age is vanishingly small. A 50µg/L limit is therefore in my view appropriate.”

However, all the other responses from this group disagreed stating that the proposed limit was too low. The Independent Scientific Committee on Drugs (ISCD) reiterated their view from the first consultation that the advice of the Expert Panel should be followed. They went on to state “Being ‘tougher’ than the evidence can support is not cost-free. It widens the net, increasing the direct costs of criminalisation to those arrested but also the indirect costs of extra prosecutions to taxpayers, and the knock-on costs to others.”

The Secretary of State’s Advisory Panel on Alcohol, Drugs and Substance Misuse stated, “Blood amphetamine concentration in drivers suspected or proven to be under the influence of the drug are universally high in the literature suggesting that a limit should be set to reflect the recreational drug use population if risk to driver safety is the prime motivation for the new offence. This argument is strengthened by the growing evidence that drivers apprehended by the police due for suspected drug-driving represent a somewhat marginalised group of experienced drug users with frequent re-arrests. To identify high risk amphetamine drivers a threshold significantly higher than 50µg/L would be more appropriate.”

An individual academic specialising as a consultant to ADHD patients also disagreed stating that “The limit is so low that it will create confusion and stigmatisation in those who take prescribed amphetamine.”

Agreed: 1 out of 4

6.5 Responses from private organisations (2) and members of the public (6):

The private organisation, a drug screening device manufacturer, stated that they neither agreed or disagreed as whilst “wholeheartedly agreed with the lower scale levels of 10µg/L or 50µg/L” queried the 50µg/L limit as suggested it could be lower and be “safer in catching and convicting more amphetamine users, or perhaps make the 50µg/L in the blood as combination of all types of amphetamine molecules.”

The other private company, Shire, specialising in the production of Lisdexamphetamine (LDX) for ADHD patients also disagreed and informed the Department that they had a number of ADHD consultants contacting them concerned that the proposed limit was too low. They stated that “Shire disagrees with the conclusion in the consultation document that, based on previous responders, 50µg/L is likely to only ‘catch’ a small number of patients. Patients appropriately prescribed LDX for the treatment of ADHD will likely have blood levels above 50µg/L. Studies demonstrate that many patients taking LDX in accordance with its approved labelling would exceed this level at certain times during the day. A pharmacokinetic study in adults administered

70mg of LDX showed that, the mean maximum plasma amphetamine plasma level was 90.1µg/L, with the level rising to 163µg/L in some patients. Based on these data and allowing for some variability in amphetamine testing, we propose an alternative limit of 200µg/L, in agreement with the opinion provided to the Department for Transport by experts in the field of ADHD outlined in section 2.9 of the response document.”

Shire also added, “The consultation document lists countries (i.e. France, Netherlands and Poland) where limits have been set at 50µg/L and other countries (Norway, Belgium, Germany and Finland) where lower limit have been set. We would like to point out that to the best of our knowledge no amphetamine based medications were licensed in any of these countries at the time these levels were set. Therefore, we question the relevance of the levels set in these countries to the UK, where both LDX and immediate release dexamphetamine (Dexedrine) have received market authorisations.”

2 members of the public also responded that they neither agreed nor disagreed, but with only 1 providing any commentary. The respondent stated, “I would ask that the proposal is considered in terms of what is the lowest level of drug (remembering that all 16 are illegal) that has an effect on human behaviour. I trust that this is probably very low since all drugs affect people in different ways and we do not want a level set that is too high for anyone since that is technically permitting drug driving.”

3 members of the public who disagreed wanted to see a zero tolerance approach and typically took the view that there should be no limit for any drug use when in charge of a vehicle.

1 member of the public stated they agreed but did not provide any comments.

Agreed: 1 out of 8

6.6 Summary

It is clear that there were 2 contrasting views. Those with an interest in enforcement and road safety largely agreed with the Government’s proposed limit or even a lower limit. In contrast those from the medical community thought that the proposed limit was too low. **Table 9** sets out a summary of the responses.

Table 9: Preferences to the proposed 50µg/L limit for amphetamine

Option	Respondents	Percentage
Agreed	8	44%
Disagreed – too low	4	22%
Disagreed – too high	3	17%
Neither agreed nor disagreed	3	17%
Total	18	100%

Whilst overall there was more support for the Government's proposed limit, the Government recognises the significant medical concerns which have been raised. The specialists in ADHD argued that it affects the ability to concentrate and whilst patients do represent an increased road safety risk when un-medicated, they are just as safe as the general population when taking their medication. These respondents also backed up these arguments with research¹³. Their concern was that prescribers and ADHD patients must not be discouraged from prescribing medication or from taking it.

Although ADHD has generally been a condition associated with childhood, changes in clinical guidelines¹⁴ mean that it is increasingly likely to be diagnosed in adults, who may also be driving. ADHD is generally treated in the first instance with methylphenidate which is not an amphetamine-type drug. However, amphetamine-type drugs, including LDX tend to be used as a second line treatment where methylphenidate is not successful.

As LDX was approved for use in the UK in February 2013 and the clinical guidelines changed in June 2013, it is too soon to say what the full impact of these changes might be, or how many drivers we might expect to see in a few years driving on our roads whilst they are taking amphetamine-type medication as a treatment for ADHD.

A further difficulty in understanding the extent of the problem was that it appeared from Shire's data that the average maximum concentration of amphetamine found in a patient taking the strongest dose of LDX could range up to 100µg/L in blood or possibly higher depending on physical characteristics. This means that some patients would be exceeding the specified limit.

The Government acknowledges that the medical community is well informed about the pharmacological implications of a limit. The Government also recognises that adult ADHD often goes undiagnosed or treatment is stopped after having it as a child and this presents real road safety risks, which need to be addressed through treatment. The proposed limit may therefore discourage those with ADHD from seeking or continuing with treatment. Shire also informed us that a common characteristic of ADHD is the difficulty in dealing with paperwork, which may have implications for the DVLA notification process and the medical defence.

It may therefore be more practical, to set a limit that is above the therapeutic range that ADHD sufferers are most likely to be on and below the limit of those most likely to be abusing medication. Setting a higher limit might mean that some abusers are not detected when they are in the 'crash/comedown' phase, but there was some evidence presented by the Secretary of State's Advisory Panel on Alcohol, Drugs and Substance Misuse that it was unlikely that significant consumption of illicit amphetamine at these relatively low levels would be seen.

¹³ E.g. 'Serious Transport Accidents in Adults with ADHD and the Effect of Medication', published the day before the consultation closed on 29 January 2014

<http://archpsyc.jamanetwork.com/article.aspx?articleid=1814941>

¹⁴ <http://www.dsm5.org/Documents/ADHD%20Fact%20Sheet.pdf>

The Government has therefore concluded that proposing a 50µg/L limit may have an adverse impact on road safety if ADHD sufferers avoid seeking treatment and therefore present an increased risk. The Government therefore will not take forward the proposed limit of 50µg/L. We will consult on a new proposed limit later in the year. Amphetamine will, therefore, not be included in the regulations that we propose to present to Parliament this spring, but will be included in further regulations once a suitable limit for amphetamine is determined.

Question 5b: Is the approach we are proposing to take when specifying the 50µg/L limit for amphetamine reasonable for those who are driving and being prescribed with dexamphetamine (which is used to treat ADHD and certain sleep disorders such as narcolepsy) and selegiline (which is used to treat Parkinson's disease)?

6.7 Response from Local Authorities and Devolved Administration (1):

The Welsh Government responded stating that the arrangements were considered to be an appropriate solution.

6.8 Responses from the Police (2):

The Metropolitan Police stated that “national road safety campaigns should also promote the new regulations. In addition, the Safer Roads Partnership will also need to review its road safety education, training and publicity programme to ensure that the regulations for the new offence is adequately publicised. In particular the interventions for young drivers will need to be updated to include information about the new drug driving offence, as well as drink driving.” The Government agrees with this view and will seek to use all possible means of communication to publicise the new offence.

Surrey Police agreed with the approach reiterating the proposals set out in the consultation and confirming, “People with these medical conditions taking dexamphetamine or selegiline legitimately will be able to rely on the statutory medical defence, and that in the view of the Police, if their driving was not impaired, then no further action should be taken.”

6.9 Responses from Partnerships and Voluntary Organisations for road safety (3):

Brake confirmed that they thought the approach was reasonable whilst RoSPA stated that, “It will be important that the relevant information is distributed to ensure that Police Officers are aware of the issues”. As stated in Chapter 7, paragraph 7.15 the Government also proposes to write to National Roads Policing to make them aware of the situation.

The South Yorkshire Safer Roads Partnership also agreed with the approach and reiterated the views expressed above that road safety education needs to be updated and the police need to be made aware.

6.10 Responses from representatives from medical, toxicology and academic organisations and individual academics (4):

The individual academic specialising as a consultant to ADHD patients responded that it was not reasonable because, “The suggested limit overlaps with therapeutic levels and will make it difficult for them to know whether or not they are over the limit, If this deters individuals from taking their medication then they may well be at increased risk of driving accidents by reason of the untreated condition.” This reiterates the academic’s earlier view. In contrast another academic thought that the approach was reasonable.

The Secretary of State’s Advisory Panel on Alcohol, Drugs and Substance Misuse stated that, “Impairment in terms of driving behaviour has not been observed in individuals prescribed low doses who take the drug in accordance with prescribing instructions.” This would suggest that these patients would not come to the attention of the police. However, they go on to say, “There is a conspicuous lack of data on how to handle cases of driving under the influence of medicinal amphetamines such that these cases may need to be handled on an individual basis.”

The ISCD responded stating, “The medical defence for those people who have been prescribed dexamphetamine or selegiline and are driving legitimately, should not enable drivers to avoid prosecution as a result of their poor driving standards.” The Government agrees with this view, which is why the section 4 ‘impairment’ offence has been retained.

6.11 Responses from private organisations (2) and members of the public (6):

The drug screening device manufacturer, stated that it was a reasonable approach but warned that the police need to be aware of “attempted deceptions.” They should therefore satisfy themselves that the driver is the person they say they are. They were also concerned, “That many people with certain conditions are not reported to DVLA by the Doctor, nor do they self-report as it quite rightly may remove their entitlement to drive.” The Government will be seeking to improve the guidance to healthcare professionals on fitness to drive as set out in the Next Steps at Chapter 10, paragraph 10.2.

Shire viewed the proposals contained in section 2.14 of the consultation relating to the Government writing to the police to make them aware of this situation as unacceptable. Shire explained, “Allowing ACPO the discretion to disseminate information ‘as they see fit’ runs the risk of compounding a policy proposal which is unsubstantiated by data with incomplete communication. We therefore strongly recommend that - with regard to patients with ADHD, the proposals contained in sections 2.12 to 2.14 are fully removed.” Depending on what limit is proposed in the future these sections may not be necessary in relation to patients with ADHD. We will though revisit this question in a further consultation.

One member of the public agreed with the approach whilst another stated, “Maybe have a sobriety test set up and expect users who are

driving to reasonably pass the sobriety test. This way any drug use/ restrictive medicines which alter the drivers' reactions could be measured and appropriate fines/bans placed." The Government does not believe this is a practical solution as a Field Impairment Test is already available to the police.

A further respondent suggested, "There should be a section on their driving licence advising police that they are allowed a limited amount of amphetamine due to their condition." As explained in Chapter 4, paragraph 4.7 we do not believe this is viable because of concerns about data protection, costs, fraud and ensuring that accurate data is maintained as patients move between different types of medication. The Government takes the view that it is in the interests of the patient to allow them to take responsibility for the information they wish to disclose and when.

The other 3 members of the public did not address this question.

6.12 Summary

In conclusion, most respondents thought that the approach was reasonable, but the Government will ask this question again when it consults again on a new proposed limit.

Question 5c: Are there any other medicines that we have not taken account of that would be caught by the limit we propose for amphetamine and the conditions they treat? This may include medicines that metabolise in the body to amphetamine. If so please give your reason(s).

6.13 Response from Local Authorities and Devolved Administration (1):

There were no comments from the respondent.

6.14 Responses from the Police (2):

There were no comments from either of the respondents.

6.15 Responses from Partnerships and Voluntary Organisations for road safety (3):

The respondents were satisfied that all the possible medicines and conditions had been considered.

6.16 Responses from representatives from medical, toxicology and academic organisations and individual academics (4):

The ISCD also pointed to LDX, which we were already aware of. They also said that "so called 'legal highs' continue to occasionally contain illegal substances including amphetamine, raising another possible way in which people may break the law without realising." We are also aware of this and have addressed so called 'legal highs' earlier.

The Secretary of State's Advisory Panel on Alcohol, Drugs and Substance Misuse also provided a list of drugs that produce amphetamine as a metabolic by-product. We have checked with the MHRA and other than LDX none are licensed for use in the UK. However, these medicines could be prescribed off-license, but as they are used at relatively low doses as an appetite suppressant, anti-depressant or as an analgesic it is unlikely they would provide a positive blood result, particularly as a higher limit than 50µg/L will be proposed. As stated in paragraph 7.5 below, when issuing a guide to type approval for preliminary drug screening devices that can detect amphetamine, the Home Office will ask manufacturers to consider cross-reactivity of structurally similar compounds when submitting devices.

The other respondents in this group were not aware of any other medicines.

6.17 Responses from private organisations (2) and members of the public (6):

None of the respondents in this group proposed any additional medicines. One member of the public did though state that all "Prescription medicines may have an effect on driving and they should seek medical opinion And only the doctor prescribing will know if that individual could be affected and once told the driver should be required to take that medical advice." Again we address this point in Next Steps at Chapter 10, paragraph 10.2.

6.18 Summary

In view of the above responses the Government is satisfied that there are no other medicines that need to be taken account of when setting a limit for amphetamine.

Question 5d: Does any business have a view on whether the Government's proposed limit will have any impact on them, directly or indirectly?

6.19 Response from Local Authorities and Devolved Administration (1):

As the devolved body is not a private business it did not offer a view on this question.

6.20 Responses from the Police (2):

Although neither a private business the Metropolitan Police said "This 'new business' will impact on capability and capacity to deal with other issues." The National Roads Policing lead raised a similar point and this is addressed at Chapter 8, paragraph 8.2. They also said that the purchase and upkeep of type approved devices both at the roadside and within custody suites will impact. The Government is aware of these costs but as stated at the outset the impact assessment does not monetise the type approval of devices.

Surrey police took a positive view of the impacts by stating, "This could lead to a potential reduction in accidents resulting in fatalities or serious

injury. The cost of investigating a fatal collision is approximately £1 million, so this could result in reduced costs. This will also have effects on stakeholders, due to reduced road closures and diversions etc.”

6.21 Responses from Partnerships and Voluntary Organisations for road safety (3):

Only the Safer Roads Partnership responded and stated, “In our discussions with various businesses responsible for employees who drive for work purposes, we are aware that some employers already conduct routine drugs tests of their staff and that a zero tolerance policy applies.”

6.22 Responses from representatives from medical, toxicology and academic organisations and individual academics (4):

None from this group offered a view on this question.

6.23 Responses from private organisations (2) and members of the public (6):

The drug screening device manufacturer asked the Government to note in relation to mobile screening devices that, “If you decide on a different saliva level from one already supplied to another Government or customer, then it will mean 6 to 12 months development and associated delay in use in the UK.” As stated earlier this impact assessment does not take account of the type approval process, but the Government notes that a possible implication of not having a limit in line with other countries may mean that there will be a need for further development costs. However, the Government believes that it is important to set a limit that is right for England and Wales.

Shire, like Napp pharmaceuticals, claimed the costs of amending their product information will have an impact on them. The Government is willing to accept that there are increased costs and has worked with Napp and Shire on estimating these costs for the revised impact assessment.

Shire were also concerned that, “If the DfT sets a level for LDX (whether 50-200µg/L) and does not set an equivalent level for methylphenidate, this could have the undesired effect of discriminating against Shire and patients appropriately prescribed and using LDX, particularly those patients whose ADHD symptoms are inadequately controlled by methylphenidate. There is also a risk that action to restrict LDX-related amphetamine levels alone (in the absence of similar action for methylphenidate may mean people wishing to abuse stimulants simply ‘switch’ from amphetamine abuse to methylphenidate abuse, confident that the levels would not be investigated in the road traffic context.”

The Government has acknowledged that it does not want to risk any ADHD patient being deterred from taking their medication given the evidence of the increased road safety risk of those who go un-medicated. This is why it is prepared to reconsider a higher limit and therefore does not believe any patient will be deterred from taking LDX. Secondly, the Government has taken the advice of the Expert Panel who have extensively reviewed the evidence and recommended the drugs for

inclusion in the regulations. The Government is also evaluating the new offence and if evidence emerges that other drugs are posing a road safety risk then it is prepared to amend the regulations.

Only 1 member of the public responded and stated, "If it will have an effect on a company then good news that they will now have to comply with the guidance and reduce crashes form drug driving."

6.24 Summary

The only additional cost that has emerged is the cost to pharmaceutical companies in amending their product information, which we address in more detail at Chapter 10, paragraph 10.2.

7. Question 6

Whether there are any other medicines that we have not taken account of that may be caught by the zero tolerance approach to 8 of the controlled drugs?

7.1 Responses from Local Authorities and Devolved Administration (4):

The Welsh Government asked us to consider so called 'legal highs'. As these do not have any medicinal use, these are not considered under this question. 'Legal highs' are addressed at Chapter 2, paragraph 2.10.

None of the local authorities had a view on this.

7.2 Responses from the Police (3):

The Police did not comment on this question.

7.3 Responses from Partnerships and Voluntary Organisations for road safety (7):

This group either provided no comment or stated that they were not aware of any other medicines that would be caught by a zero tolerance approach.

7.4 Response from approved driving instructors (2):

Again there was no comment on this aspect.

7.5 Responses from representatives from medical, toxicology and academic organisations and individual academics (29):

A forensic laboratory, the British Pain Society, Royal Pharmaceutical Society and The Pharmacy Association all pointed out that a small number of patients were prescribed ketamine for persistent pain.

Pharmacy Voice commented that there were some ex-substance misusers who did not tolerate methadone or other opioid substitutes and were prescribed diamorphine. The Sickle Cell Society also commented that some sufferers were also given diamorphine by clinics. Diamorphine would be detected by a zero tolerance approach to 6-MAM.

A toxicologist informed us that selegiline has methylamphetamine as a metabolite, which might trigger a positive result for amphetamine. Selegiline is used to treat Parkinson's disease and it may be that some patients may still be driving in the early stages of the disease. The Government agrees that this could be a possibility. As Parkinson's disease is a condition that is required to be notified to the DVLA the Government proposes to offer the same solution as proposed for Sativex and this is discussed below in paragraphs 7.9 to 7.15.

The toxicologist also pointed out that mebeverine may cause a positive result for amphetamine in a preliminary drug screen in saliva if a zero tolerance approach was taken. Mebeverine's major therapeutic role is in the treatment of irritable bowel syndrome (IBS) and associated abdominal cramping. The Government is not proposing to take a zero tolerance approach to amphetamine so in the unlikely event of a mebeverine user providing a positive preliminary screening result, it is further unlikely that a sufficient amount would metabolise into amphetamine in blood so would not provide a positive evidential blood test result. However, the Government does not want any mebeverine user to be inconvenienced by providing a positive preliminary screening result. When issuing a guide to type approval for preliminary drug screening devices that can detect amphetamine, the Home Office will ask manufacturers to consider cross-reactivity of structurally similar compounds when submitting devices.

The Pharmacy Substance Misuse Advisory Group also remarked that though extremely rare, cocaine is used as a legitimate ingredient in some ophthalmological preparations where eye drops with a solution of 4% cocaine with maybe 1 or 2 drops were used in outpatient departments as part of a diagnostic procedure. The eye drops are used for Horner's Syndrome, which is the drooping of the eyelids and reaction to light. It may be that some of these patients will not be driving due to their eye condition, but even if they were, it is highly unlikely they would provide a positive result for cocaine given the low levels of cocaine used in the solution.

The Pharmacy Substance Misuse Advisory Group also advised that cocaine is used, again extremely rarely, for maxillofacial surgery for head and neck cancers and for packing the nose in extreme cases of nasal blood loss, where a nasal spray is used in an operating theatre situation with a solution of 10% cocaine. It is highly unlikely that a person would provide a positive test result for cocaine after such a small dosage and given the time needed to recover from surgery as the window of opportunity for testing cocaine for a single dose according to the Expert Panel report is between 3.5 and 7 hours¹⁵.

The medicines and the conditions they are treating and how the Government proposes to deal with them is set out in paragraphs 7.9 to 7.15.

7.6 Responses from private organisations (5) and members of the public (38):

Only one member of the public responded to this question, pointing out that Bedrocan, Bedrobinol, Bediol, and Bedica are all types of herbal medicinal cannabis that can be prescribed in Europe and Europeans can bring to the UK and legally consume.

If a resident of Belgium or the Netherlands has been legitimately prescribed herbal cannabis in one of those two countries where it is licensed as a medicine and has legally brought that medicine into the UK, then in the event of a drug driving offence being suspected in Great

¹⁵ Page 77 of the Expert Panel report '*Driving under the influence of drugs.*'

Britain, they would still be able to claim the medical defence in the same way a Sativex user would be. This is provided their driving is not impaired where the section 4 offence would be applied. Such cases, though, are likely to be extremely rare.

A drug screening device manufacturer warned that codeine is an addictive medicine, which can be metabolised to morphine and therefore drivers could be using it above a therapeutic level and above the Government's proposed morphine limit. The respondent also thought that drivers could try to mask real opiate use such as heroin, by declaring a codeine based medication as an excuse for a positive screen. Codeine can be bought over the counter as well as being prescribed.

Our view on codeine is that the Expert Panel's recommended limit for morphine is above the concentration which would normally be found in a driver taking over the counter codeine. Police are likely to begin any drug driving investigation by considering evidence of impairment since if impairment is present, issues of medical defence, therapeutic levels and specified limits do not apply. If impairment was not present and in the unlikely event the police carried out a drug screening test and the driver provided a positive result and police suspected that the drug being used was supplied over the counter but being used above its intended dose the driver would probably be arrested. If a blood specimen was then taken and found to contain morphine above the specified limit and the driver was not able to satisfy police that the drug was being used as prescribed or directed, a prosecution for the new section 5A drug driving offence could follow and the matter would be for a court to determine. Equally if the blood specimen found 6-MAM (heroin or diamorphine) after taking codeine to mask their heroin use and the driver was not able to satisfy that they had been prescribed diamorphine, a prosecution for the section 5A offence could also follow.

We believe that such cases would be very rare. Unless a person's driving was impaired or they have been involved in a collision they are unlikely to come to the notice of police. If the person was impaired police are likely to begin by arresting the person for impairment under the existing law and a screening test at that stage would be superfluous. In normal circumstances both the section 4 offence and the new section 5A offence would then be investigated at the police station. If a driver professes that his drugs have been taken as prescribed, it seems likely that police would simply confine their enquiries into the impairment offence rather than engage in establishing the truth or otherwise of the medical defence to the section 5A offence.

Napp Pharmaceuticals stated that whilst they did not offer up any additional drug that may be detected by a zero tolerance approach if the Government was to introduce any new drug to the drug driving regulations in future it would need evidence to justify. The Government agrees with this view and have set out elsewhere in the document that its evaluation will be seek to make any future decisions on the inclusion of any other drugs will be evidence based.

7.7 Responses from public bodies (3):

Only the DVLA responded to this question and stated that they had been contacted by a pain management clinic that occasionally prescribed ketamine.

7.8 Responses from voluntary organisations in the drugs field (3):

None of these organisations offered any further medicines that would be caught under the proposed zero tolerance approach.

7.9 Summary

The consultation has revealed a number of other medicines as well as Sativex that could be caught under the proposed zero tolerance approach and potentially for the 50µg/L limit proposed for amphetamine. These are:

Ketamine – neuropathic pain

Diamorphine (6-MAM) – Sickle Cell & opiate dependent substitute

Selegiline (methylamphetamine and/or amphetamine) – Parkinson's disease,

Mebeverine (amphetamine) – Irritable Bowel Syndrome

Amphetamine – ADHD and Narcolepsy

Before discussing these drugs, it is worth clarifying that the main objective of including medicinal drugs in the new offence is to remove from our roads drivers who have obtained these drugs illegally and present a risk to themselves and other road users. Where patients who are taking prescription medication have a concentration of a drug in their body which is over the limit, the medical defence would be open to them if they were taking the medication in accordance with the instructions of a healthcare professional and their driving was not impaired.

7.10 Ketamine

Ketamine is used for the control of acute neuropathic pain where other treatments have failed. Neuropathic pain is not a notifiable condition so the DVLA would not be able to send a letter to a patient or the person who notified the DVLA, e.g. their GP. However, ketamine is only used under the controlled supervision of a pain management clinic. The Department is therefore working with the Department of Health to specifically target these clinics in making them aware of the new offence. We will also be asking clinics to ensure that patients are aware that the statutory medical defence is available to them and if they are not impaired to drive then they need to be prepared to provide evidence of their legitimate medical use of ketamine if they were to be stopped by the police. We will also reassure clinics that the National Roads Policing lead has stated that the police will take all reasonable steps to avoid inconvenience to any prescribed users. The position for those on medication, therefore, does not change from the current position.

7.11 Diamorphine

Any mobile screening device would seek to support a positive evidential blood limit of 80µg/L for morphine, which is set at a road safety risk

based limit. Patients taking diamorphine would therefore only provide a positive preliminary screening result if they were on a dose of diamorphine that exceeded the higher morphine limit. In this scenario, the police are likely to ask if the driver is taking any medication, which might affect the result. At this point the driver should declare their use of diamorphine and be prepared to provide evidence of their prescription.

The Department will though be working with the Department of Health to provide advice to patient groups such as the Sickle Cell Society and drug rehabilitation charities so that they can advise their members about the law. In addition, the MHRA will be providing advice to the medical profession, as set out at Chapter 10, paragraph 10.2.

7.12 Selegiline

The metabolic pathway may result in persons taking selegiline testing positive for amphetamine and/or methylamphetamine on drug screening tests. Both the Department for Transport and the Department of Health will, again, work with patient groups to raise awareness of this issue. However, Parkinson's disease is a condition which is required to be notified to the DVLA. As part of responding to a notification, there is then an opportunity for the DVLA to directly inform patients and their GPs about the new offence and to ask them to be prepared to show evidence of being prescribed the medicine in the same way as set out for Sativex in the consultation.

7.13 Amphetamine

Amphetamine is used for the treatment of ADHD and narcolepsy, both of which are notifiable conditions. There is then the same opportunity for the DVLA to directly inform patients and their GPs.

7.14 Mebeverine

As discussed above it is unlikely that mebeverine would be above the proposed limit as the Government is not proposing a zero tolerance approach. It is also unlikely to metabolise into a positive evidential blood result for amphetamine but potentially could provide a positive result for a preliminary oral fluid screening test. When issuing a guide to type approval for preliminary drug screening devices that can detect amphetamine, the Home Office will ask manufacturers to consider cross-reactivity of structurally similar compounds when submitting devices.

7.15 Conclusion

For the notifiable conditions of multiple sclerosis, ADHD, narcolepsy and Parkinson's disease the Department has agreed with the DVLA and the Department of Health that once the return letter has been sent to the GP they will also send a letter to the driver to confirm the duration of the licence and will add a note which states:

““If you are currently being treated with or start being treated with Sativex/dexamphetamine/selegiline [to be deleted as appropriate] please be aware that it may be helpful to keep confirmation of this with you when you are driving. This is because the police have new powers to investigate drivers who are suspected of driving with such substance(s) in their bodies. If the police are satisfied that you are taking it under the

supervision and/or advice of a healthcare professional (such as the prescriber, your doctor or pharmacist) and your driving is not impaired, they can allow you to proceed. Documents that you may find helpful to produce could include a prescription, counterfoil or any letter, report or advice from a healthcare professional. Please note that it remains your responsibility to refrain from driving if the medicine you are taking adversely affects your driving.”

For the non-notifiable conditions of neuropathic pain where ketamine is very occasionally administered and Sickle-cell disease where diamorphine is also occasionally administered, DVLA will add the following advice to their ‘At a Glance’ pages:

“If you are currently being treated with or start being treated with diamorphine or ketamine, please be aware that it may be helpful to keep confirmation of this with you when you are driving. This is because the police have new powers to investigate drivers who are suspected of driving with such substance(s) in their bodies. If the police are satisfied that you are taking it under the supervision and/or advice of a healthcare professional (such as the prescriber, your doctor or pharmacist) and your driving is not impaired, they can allow you to proceed. Documents that you may find helpful to produce could include a prescription, counterfoil or any letter, report or advice from a healthcare professional. Please note that it remains your responsibility to refrain from driving if the medicine you are taking adversely affects your driving.”

The DVLA intends to commence the use of the above wording into letters for notifiable conditions with immediate effect, as patients may be issued with a licence with a duration of 3 years, so it is prudent to start that advice now. The regulations still need to be agreed by Parliament, but the Government intends to proceed now, since this advice is still relevant for the existing impairment offence as well as in promoting understanding of the new offence.

The Government also proposes to write to

National Roads Policing to make them aware of the above situation. It will be for the police to disseminate the information as they see fit to ensure that police officers are aware that some of those suffering from the above conditions could be taking the above medications and therefore may be driving legitimately.

Changes to medicines information must be made through the marketing authorisation via the Medicines Healthcare products Regulatory Agency (MHRA) and should be in line with the provisions of Title V of Council Directive 2001/83/EC. The MHRA informed the marketing authorisation holders (MAH) in December 2013 that they must amend their product information. The letter to the MAHs can be seen on the MHRA’s website at:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON350699>

The Department for Transport and the Department of Health will also be working with patient support groups to ensure that these patients are aware of what they need to do if they wish to continue driving.

The Government believes this approach is reasonable and will not deter any of the above sufferers from taking their medicine in order to continue driving provided they are not impaired to do so.

8. Question 7

Views on whether there was any additional evidence to improve the costs and benefits set out in the impact assessment?

8.1 Responses from Local Authorities and Devolved Administration (4):

Only the Welsh Government commented on this question and urged caution on the methodology used to estimate drug driving casualties provided for each option, given that the quality of Hospital Emergency Department data sets can vary considerably.

8.2 Responses from the Police (3):

Both the National Roads Policing lead and the Police Liaison Office at the Welsh Government responded that they thought the estimate of 8,800 prosecutions a year for the new offence was likely to be an over-estimate. They concurred with our methodology in only considering a percentage of those drug drivers who may still be evident after providing a negative alcohol breath test. This was because the complexity, cost and time involved for drug drive investigations is greater than that for alcohol but the sentencing is the same whichever offence is pursued.

However, the National Roads Policing lead also pointed out that “the budget reductions necessary over the past 12 months or so has had a substantial effect on all areas of policing, including roads policing..... This will undoubtedly have a real impact on preventative policing such as drug driving and any expected increase will inevitably not occur or be affected.”

The operational application of police resources across all criminal justice responsibilities is for Chief Officers and will vary at different times according to many factors. Roads policing and the enforcement of drug driving in particular will need to be resourced so that it is commensurate with other duties. It is intended that the new offence will be more objective than the current offence and for that reason it will be more effective and easier to enforce.

The Police Liaison Office at the Welsh Government also stated that “the methodology used to estimate drug driving casualties provided for each option appear to be utilising the most appropriate data sources, other than an observation on the quality of Hospital Emergency Department data sets. Where hospitals differ is the extent that they record or note the aetiology or the cause of injury, or reason for attendance at the Emergency Department. In the case of drug driving often the result of a Road Traffic Collision and current data may not reflect the true picture with anecdotal suggestions of under reporting.”

The impact assessment recognises that the casualties officially recorded in the contributory factors are likely to be an under-estimate, which is why a range of outcomes was provided.

8.3 Responses from Partnerships and Voluntary Organisations for road safety (7):

Only the Institute of Advanced Motorists and the Royal Society for the Prevention of Accidents responded to this question. Both stated that a thorough and comprehensive analysis had been provided and they could not provide any additional information. None of the others responded to this question.

8.4 Responses from approved driving Instructors (2):

There were no comments from either of the respondents in this group.

8.5 Responses from representatives from medical, toxicology and academic organisations and individual academics (29):

The Independent Scientific Committee on Drugs thought that “the evidence is poor to non-existent that increased toughness or liberality of drug laws communicates ‘messages’ to drug users that affect behaviour.” The Government believes that the evidence provided from Europe and from the DRUID Final Conference in 2011 in reference to a study in Germany is sufficient to show that “the more likely a person thinks a police stop will be, the more often the person decides against drug driving”. Further, Elvik’s model¹⁶ on the deterrent effect is a well-regarded road safety model which provides clear evidence on this point.

As stated in paragraph 2.10, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) also suggested that recent research in Germany and the USA showed that one of the most cited motivations by young people for consuming synthetic cannabinoids was to avoid detection in drug tests. The EMCDDA recommended that the potential implications of drug users moving to other drugs to avoid detection should be considered in the next impact assessment.

It would be difficult to monetise changes in drug taking behaviours and its impact on road safety in the next impact assessment as there is not any evidence available to base any estimates on.

8.6 Responses from private organisations (5) and members of the public (38):

Only 1 member of the public commented on the impact assessment and said that “the whole thing is guesswork at best and thus should be declared null and void.” In contrast one of the private organisations stated “You have to calculate it somehow but rather than pondering how accurate you are in whether or not it is cash neutral or cash positive it might be, let’s get on with the process and see just how successful it really is.”

¹⁶ Elvik, R. 2001. “Cost-benefit analysis of police enforcement.” Working Paper 1, Enhanced Safety Coming from Appropriate Police Enforcement (ESCAPE), Project funded by the European Commission under the Transport RTD Programme of the 4th Framework Programme. Institute of Transport Economics, Oslo, Norway.

The novelty of this offence means that, in assessing it, the Government can only look at evidence from other countries and make some assumptions as to the impact in England and Wales. The Government is seeking to bring the new offence into force swiftly, which will mean that actual data on the impact will be available as soon as possible.

8.7 Responses from public bodies (3):

Only the CPS responded to this question and stated they accepted the basis for the estimated number of additional prosecutions as reasonable. However, they observed that if the legislation meets its policy objective, the deterrent effect may well reduce the number of prosecutions and the associated costs in future years.

8.8 Responses from voluntary organisations in the drugs field (3):

Release was the only organisation in this group to respond to this question. They suggested that because of the likelihood of people having to prove the medical defence it was incorrect to make comparisons with the legal aid provisions for drink driving. They stated that “the likelihood of being granted legal aid as a defendant in these sort of proceedings is minimal if viewed in the same way as drink driving cases which are not publicly funded save for exceptional circumstances..... as in reality there will be an increase in people representing themselves which has a knock on effect in terms of delays and extended proceedings. “

The Government believes that, in making the comparison with drink driving, the impact assessment used the best data available to come up with a projection.

Release also stated particularly in relation to their concern that ethnic groups may be targeted that “there is a significant risk that this new offence will cause hundreds of thousands of citizens to be subjected to roadside drug tests with little positive impact.” These concerns are considered in paragraph 2.10.

Release also sent us their views on the difficulties in testing for drugs particularly in using alternatives to blood. The impact assessment explicitly did not consider the costs of screening devices and so these views cannot be incorporated in any update. However, the Department has passed Release’s concerns to the Centre for Applied Science and Technology at the Home Office as they are responsible for type approving screening devices.

8.9 Summary

Only around 10% of respondents made any contribution to this question. There were some positive responses to our analysis so far, but the Government recognises these were only estimates and the proof will be in the actual data the Department will be collecting as part of the evaluation of the new offence. The evaluation contract was awarded in October 2013. The research team are currently scoping the research and will soon be collecting baseline data. They will be monitoring the offence until spring 2016.

The Government will take account of these responses as we seek to refine the impact assessment in readiness for the next parliamentary stage.

9. Question 8

Whether any business believes the proposals will have any impact on them?

9.1 Responses from Local Authorities and Devolved Administration (4):

As none of these are private businesses they did not offer a view on this question.

9.2 Responses from the Police (3):

As none of these are private businesses they did not offer a view on this question.

9.3 Responses from Partnerships and Voluntary Organisations for road safety (7):

Both RoSPA and the Institute of Advanced Motorists stated that they will need to update their road safety advice and materials to help raise awareness of the new offence. RoSPA also said that they will help promote the 'do not take drugs and drive' message. The Government believes this is out of scope of the impact assessment as these 2 organisations are charities who review their road safety advice depending on whatever is topical or what they consider needs attention.

The Road Safety Partnership suggested that "this new legislation could create an increase of those accessing community drug treatment systems." But they did add there would be the following benefits:

- Increase in those not known to drug treatment services and those who would be unlikely to access drug treatment services coming into contact with drug treatment services and reducing their substance misuse.
- Reduction in offending behaviours associated with Class A substance misuse when engaged in treatment.
- Increase in prevention work and early diagnosis of Blood Borne Virus's (BBVs), which would have a positive impact on public health and safety and a reduction on spending in treating BBVs.
- Reduction in anti-social behaviour in local areas.

However, the Partnership did counter the above with a possible dis-benefit of "an increase in work load for drug treatment providers with an unlikely increase in funding." As discussed in Chapter 3, paragraph 3.3, Graham Evans MP introduced to Parliament the 'Drug Driving (Assessment of Drug Misuse)' Bill. The Home Office produced a separate impact assessment in which it stated there would be a net annual benefit of £9million.

The AA said they would like to be involved in any future High Risk Offenders (HRO) scheme through their DriveTech Steer Clear programme. This is not considered as an impact upon their business as it is an offer of assistance. The Government would like to acknowledge this kind offer. At present, The Government does not anticipate introducing an HRO scheme until after the evaluation of the new offence is completed in spring 2016.

9.4 Responses from Approved driving instructors (2):

1 driving instructor said that the new offence would have a positive impact on their business as drug drivers “pose a daily threat to myself and those I am attempting to teach to drive.”

The other driving instructor did not give a view.

9.5 Responses from representatives from medical, toxicology and academic organisations and individual academics (29):

1 of the forensic laboratories, ROAR Forensics stated “the proposals will have a major impact (on the forensic industry) especially within the current situation of a lack of experienced toxicologists following the closure of the Forensic Science Service and continuing challenges in resources and in turnaround time expectations within the national forensic framework agreement.”

The laboratory cited a range of additional costs the forensic industry would incur to provide this service, including the cost of initial research and development work to develop testing methods and seeking the relevant accreditations (e.g. from the UK Accreditation Service). These costs, the respondent said, would result in an increase in a charged cost to the police for the work to be undertaken, as their costs in providing the service would increase.

The laboratory also thought that there would be an increase in the need to attend court to give evidence in such cases. This would, they said, further reduce expert witness and report writing resource within forensic companies, negatively impacting on workload and potentially producing case backlogs, lengthening overall turnaround time for all their customers, including HM Coroners.

The Government believes that it is for the laboratories to determine whether it is in their commercial interests to provide a service, taking all relevant factors into account, and to price their services competitively. Police forces already choose to contract to the laboratory that provides the service which best suits their needs and the Government expects this to continue.

A number of patient support bodies remarked that the new offence may have an impact on individuals whose work requires them to drive (e.g. lorry drivers); and who also take medication e.g. analgesics for pain relief. They thought that this could have consequences for businesses that employ them, as if these drivers stop taking their medication, their sickness absence may increase. The Government does not believe that patients will need to worry if they are taking their medication in

accordance with medical advice. We have set out our proposed approach to making this clear at Chapter 10, paragraph 10.2.

Another patient support group suggested that an unintended consequence of the new legislation might be that alternatives to morphine could be prescribed, which are more expensive and will thus have a significant impact on health expenditure. It is for healthcare professionals to decide which drug is best for their patient, taking into account all relevant factors. The Department is working with the MHRA and the Department of Health to ensure that healthcare professionals are informed well in advance of the commencement of the new offence and this is discussed in more detail at Chapter 10, paragraph 10.2.

An NHS Hospital Trust suggested that there could possibly be an impact upon healthcare providers to ensure patients know when they should not drive. They also suggested “there may be an impact on the health provider, NHS Trust or other provider’s liability if they are found to be in breach of providing the necessary information to a patient prescribed these medications which then led to a road traffic accident.” The Government takes the view that the responsibility for driving ultimately rests with the driver and the responsibility for the healthcare professional is to bring to the attention of the patient the question of fitness to drive.

We will consider how such concerns could be minimised when developing a communications plan at Chapter 10, paragraph 10.2.

9.6 Responses from private organisations (5) and members of the public (38):

Napp Pharmaceuticals set out in their response that there will be a cost to change Patient Information Leaflets (PILs) and packaging; and that they will need sufficient time to make these changes. The Department therefore consulted with the MHRA who advised that “since scientific evidence has been provided to inform on the risk related to driving and risk minimisation has been put in place within the UK, through the amendment to the Road Traffic Act, marketing authorisation holders (MAHs) are required under directive 2001/83/EC as amended, to update their summary of product information (i.e. vary their licence details) and patient information to include that information with respect to effects on driving.”

Despite the above statement the Department agrees that there are some small additional costs to the MAHs. It has, therefore, worked with the MHRA and Napp Pharmaceuticals to monetise these costs and will include them in a revised impact assessment.

Napp also stated that if the communications and guidance is insufficient then healthcare professionals may stop prescribing some medicines, which will impact on some drug companies’ profits. Reckitt Benckiser Pharmaceuticals were similarly concerned with this. This concern is similar to that expressed by patient support groups at paragraph 9.5 and the Government’s response is set out there and in paragraph 10.2.

A drug screening device manufacturer commented that overall the proposals will have a positive impact upon their business through sales of roadside screening devices to police forces. In addition, they thought

that “once the Government is seen to be doing something at the roadside that corporate market will also grow significantly as many other companies will either see the need, or will feel left behind if they are not screening.”

They went on to say that they thought that organisations would “gain from fewer accidents and see their main savings come from fewer “unexplained” incidents of damaged vehicles from misjudgements whilst driving, and hence not be paying for employee and vehicle down time, vehicle repairs, deliveries not met etc.”

Only one member of the public commented on this aspect, taking the view that the Government was safeguarding the profits of the drug manufacturers by proposing a higher limit for medical drugs.

9.7 Responses from public bodies (3):

2 public bodies commented on the impact on them, although neither organisation is in the private sector, so they are not relevant when estimating the cost to business.

The DVLA stated that they would need to make IT changes to capture these new offenders, but this was in progress and would be delivered in time for the introduction of the new offence. New medical examinations would also need to be set up for when offenders reapply for their licence. The DVLA were also concerned that the police might start asking them to deal with cases where a person’s driving was impaired, rather than take them to court due to the difficulties in proving impairment. This is unlikely to increase as the new offence will reduce the need to consider impairment.

The CPS commented that the new offence will provide the CPS with a useful alternative option to the existing offence. However, they reiterated their concerns about the need to deal robustly with spurious claims of medical reasons why blood cannot be provided, otherwise the CPS will have a far more difficult task in securing a conviction. As stated in Chapter 3, paragraphs 3.2 and 3.9 the Government will work with the police to address this.

9.8 Responses from voluntary organisations in the drugs field (3):

There was no response on this aspect.

10. Next Steps

10.1 Regulations

As all of the responses to the consultation have been considered and the Government has concluded that its proposals are broadly supported, the regulations will therefore be finalised with the drugs and their limits as set out in Table 6.

The Government will shortly be submitting the draft regulations to the Joint Committee for Statutory Instruments and seek a Parliamentary slot to present these regulations to Parliament so they can be debated and voted upon under the affirmative procedure.

Subject to Parliamentary approval the new offence is expected to come into force later in 2014.

10.2 Communications to patients

The Government recognises the importance of providing consistent and comprehensible messages to patients, their representatives and healthcare professionals. This Chapter describes how we propose to ensure this happens.

Communication of the implications for individual medicines

The Department for Transport is working with the Department of Health and the MHRA, who are responsible for regulating medicines and their product information, to ensure that there are clear messages accompanying medicines for patients and clear messages for healthcare professionals.

MHRA have already provided new wording on driving for Market Authorisation Holders (i.e. pharmaceutical manufacturers) for relevant medicines. Such wording will be inserted into Patient Information Leaflets (PILs) and included in the 'Summary of Product Characteristics', written for healthcare professionals and covers the information which is known about a particular medicine and the potential to affect the patient's ability to drive. The notification of the proposed new wording is available at: <http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON350699>

In addition, the MHRA will take the following steps:

- work with the compilers of the British National Formulary, a key source of information for healthcare professionals to update it with additional information on drugs and driving;
- further development Continuing Professional Development training modules for healthcare professionals;

- provide new information in the monthly edition of 'Drug Safety Update', viewed by healthcare professionals and may also include specific articles directed for patients

Communication to healthcare professionals

The Government proposes to work with the relevant medical and pharmacy Royal Colleges to develop common guidance that will be available to healthcare professionals of affected medicines. This will include guidance on the issues to consider when advising a patient about driving. Such advice can be particularly important for the start of medication and concerning any changes in dose, when patients can be at most risk of being affected.

Healthcare professionals should, when appropriate advise patients how to properly take account of possible side effects of their medicines and on the need to refrain from driving if they may be impaired. However, it is important to emphasise that it is the responsibility of patients to take account of such appropriate advice received in deciding whether or not to drive on any particular occasion.

It is not possible to relate doses of medicines taken to precise blood levels. As with alcohol, everyone is affected differently by drugs; and specific blood-drug levels will depend on a number of factors, including the identity of any substance taken, the strength of that dose and differences between individuals in drug metabolism. If patients want to know how to identify whether they may be impaired to drive on their medication, they can discuss it with a healthcare professional and can read written advice provided alongside their medication.

Communications to patient groups

We will also use the guidance for healthcare professionals to develop guidance for patient groups so that they can advise their members about the new offence. This will be particularly important where patients may be taking medication which attracts a zero tolerance limit.

Communication via the DVLA

We will also work with the DVLA to ensure that they provide guidance to patients. As set out in Chapter 7, paragraph 7.15, this will include writing to patients who report a notifiable medical condition and who may be prescribed medication which could result in them exceeding the specified limit. We will also work with the DVLA to develop some general guidance on the new offence which could be used on relevant web pages and leaflets.

10.3 Communications to the wider public

The Government has a statutory duty to inform the public about any changes in legislation. Consequently, the Department is developing a communications campaign that will seek to raise awareness of the changes in the drug drive legislation amongst the adult population.

Annex A: List of replies to the main consultation

A.1 Local Authorities and devolved administration (4):

Buckinghamshire County Council
Mayor's Office for Policing and Crime (London)
Transport for London
Welsh Government

A.2 Police and Police Associations (3):

National Roads Policing
Police Liaison Office at the Welsh Government
West Yorkshire Police

A.3 Road safety partnerships and organisations (7):

BRAKE
Institute of Advanced Motorists
Living Streets
RoadPeace
RoSPA
Safer Peterborough Partnership
The AA

A.4 Driver trainers (2):

Ann Moyes
Martin Sisson

A.5 Representatives from medical, toxicology and academic organisations and individual academics (29):

British Medical Association
Carmarthenshire Locality Office – Wales NHS
College of Mental Health Pharmacists
Chronic Pain Policy Coalition
Dr Ben Sessa
Dr Rob Tunbridge
Dr Thomas Frain
Dr Willy Notcutt

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
Faculty of Pain Medicine, Royal College of Anaesthetists
Independent Scientific Committee on Drugs
LGC Forensics
National Rheumatoid Arthritis Society
Niall Scott - Forensic psychologist
Pain UK
Pharmaceutical Services Negotiating Committee
Pharmacy Substance Misuse Advisory Group
Pharmacy Voice
Richard Evers
ROAR Forensics
Royal College of Psychiatrists in Wales
Royal Pharmaceutical Society
Sheffield Teaching Hospitals NHS Trust
Sickle Cell Society
Shingles Support Society
South Tyneside NHS Foundation Trust
The British Pain Society
The Secretary of State for Transport's advisory medical panel on alcohol, substance misuse and drugs in driving
The United Kingdom Clinical Pharmacy Association

A.6 Responses from private organisations (5) and Members of the Public (38):

Association of British Insurers
Draeger (manufacturer of Drug detection devices)
Dtec (manufacturer of Drug detection devices)
Napp Pharmaceuticals
Reckitt Benckiser Pharmaceuticals

Abigail Watkins-Kazan
Alasdair Whyte
Andrew Churchill
Bert Morris
Cameron Raw
Chris Bovey
Chris Cooma

Chris Rutherford
Chris Stephens
D Worrall
Elliot Radley
Eric Pritchard
Greg Foreman
Guy Maxwell
Ian Davies
Jack Howell
James Moulang
James Williams
Keith Benham
Leon Delan
Liz Muskin
Matthew Barlow
Meic Bromwell
Michael Evans
Mike Thompson
Paul Ireland
Peter Crowe
Peter Glenn
Peter Reynolds
Robin Hood
Robin Moncaster
Sarah Christie
Sarah Martin
Simon Ritchie
Thomas Haplin
Timothy Moore
Tony Hewitt
Unnamed constituent of Stephen Williams MP

A.7 Responses from public bodies (3) and voluntary organisations in the drug field (3):

Chief Fire Officers Association
Crown Prosecution Service

DVLA

Drug Equality Alliance

Release

UK Cannabis Internet Activists

Annex B: List of replies to the public consultation on a proposed limit for amphetamine

B.1 Local Authorities and devolved administration (1):

Welsh Government

B.2 Police and Police Associations (2):

Metropolitan Police

Surrey Police

B.3 Road safety partnerships and organisations (3):

Brake

Royal Society for the Prevention of Accidents (RoSPA)

South Yorkshire Safer Roads Partnership

B.4 Representatives from medical, toxicology and academic organisations and individual academics (4):

Dr Rob Tunbridge

Independent Scientific Committee on Drugs

Professor Eric Taylor

Secretary of State's Advisory Panel on Alcohol, Drugs and Substance Misuse

B.5 Responses from private organisations (2) and Members of the Public (6):

Dtec (manufacturer of Drug detection devices)

Shire

Adrian Davies

Allen Stark

Arvine Bird

Chris Bovey

Graham Shepherd

Les Owen

Annex C: Summary analysis of responses to the main consultation

	LA, devolved and public bodies		Police		Road safety & drug field orgs		Driving Instructors		Medical, Toxicology Academics		Private orgs & public	
		%		%		%		%		%		%
Q1												
Yes	7	100	3	100	6	60	1	50	17	59	8	19
No	0	0	0	0	4	40	1	50	9	31	34	79
No view									3	10	1	2
Q2												
Option 2	0	0	0	0	2	20	0	0	3	10	5	12
Option 3	0	0	0	0	0	0	1	50	2	7	1	2
No view									7	24	29	67
The percentages to the above 2 questions are combined to 100% so a true reflection of the preferred options is provided, e.g. for medicine & academia 61% for option 1, 11% for option 2, 7% for option 3 and 24% no view												
Q3												
Yes	5	100	2	100	4	100	1	100	16	94	4	80
No	0	0	0	0	0	0	0	0	1	6	1	20
No comment	2		1		6		1		12		38	
Q4												
Yes	5	100	3	100	5	71	0	0	12	80	3	60
No	0	0	0		2	29	1	100	3	20	2	40
No comment	2				3		1		14		38	
Q5												
600	1				2				1			
300									1			
100			1						1			
50	1				1				2		1	
Zero	1		1		2		1		1			
No comment	4		1		5		1		23		42	
Q6												
Ketamine	1								4			
Diamorphine									2			
Amphetamine based									2			

Cocaine									1			
No comment	6		3		10		2		20		43	
Q7												
Yes (can improve IA)	2	100	2	100	1	33	0	0	3	75	1	50
No (can't improve IA)	0	0	0	0	2	67	0	0	1	25	1	50
No comment	5		1		7		2		25		41	
Q8												
Yes (impact on business)	0	0	0	0	1	100	0		6	100	1	33
No	0	0	0	0	0	0	1	100	0		2	66
No comment	7		3		9		1		23		40	

No comment also includes out of scope responses

Annex D: Consultation questions

Q1. Do you agree with the Government's proposed approach as set out in policy option 1? If not please provide your reason(s).

Q2. Do you have any views on the alternative approaches as set out in policy option 2 and 3?

Q3. We have not proposed specified limits in urine as we believe it is not possible to establish evidence-based concentrations of drugs in urine which would indicate that the drug was having an effect on a person's nervous system. Do you agree with this (i.e. not setting limits in urine)? Is there any further evidence which the Government should consider?

Q4. Is the approach we are proposing to take when specifying a limit for cannabis reasonable for those who are driving and being prescribed with the cannabis based drug Sativex (which is used to treat Multiple Sclerosis)? If not what is the evidence to support your view?

Q5. Do you have a view as to what limit to set for amphetamine? If so please give your reason(s).

Q6. Are there any other medicines that we have not taken account of that would be caught by the 'lowest accidental exposure limit' we propose for the 8 illegal drugs? If so please give your reason(s).

Q7. Are you able to provide any additional evidence relating to the costs and benefits associated with the draft regulations as set out in the Impact Assessment? For example:

- Do you have a view on the amount of proceedings likely to be taken against those on the medical drugs proposed for inclusion under the approach in Policy Option 1? If so please give your reason(s).
- Do you have a view on the methodology used to estimate the amount of proceedings? If so please give your reason(s).
- Do you have a view on the methodology used to estimate the drug driving casualties' baseline? If so please give your reason(s)
- Do you have a view on the methodology used to estimate the casualty savings? If so please give your reason(s).
- Do you have a view on the methodology used to estimate those arrested on a credible medical defence under Policy Option 3? If so please give your reason(s).

Q8. Does any business have a view on whether the Government's proposals will have any impact on them, directly or indirectly? If so please give your reason(s).

Amphetamine Consultation Questions:

Q1. Do you agree with the Government's proposed limit for amphetamine? If not please provide your reason(s).

Q2. Is the approach we are proposing to take when specifying a limit for amphetamine reasonable for those who are driving and being prescribed with dexamphetamine (which is used to treat ADHD and certain sleep disorders such as narcolepsy) and selegiline (which is used to treat Parkinson's disease)? If not what is the evidence to support your view?

Q3. Are there any other medicines that we have not taken account of that would be caught by the limit we propose for amphetamine and the conditions they treat? This may include medicines that metabolise in the body to amphetamine. If so please give your reason(s).

Q4. Does any business have a view on whether the Government's proposed limit will have any impact on them, directly or indirectly? If so please give your reason(s).