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Drug Driving: Proposed Regulations – Analysis of Consultation Responses

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DRUG DRIVING: PROPOSED REGULATIONS – ANALYSIS OF CONSULTATION RESPONSES

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The views expressed in this report are those of the researcher and do not necessarily represent those of the Scottish Government or Scottish Ministers.

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NOTE

Throughout this report, ‘the Government’ will refer to the Scottish Government unless otherwise stated.

EXECUTIVE SUMMARY

1. In 2013, the UK Government and Scottish Government undertook a joint public consultation about proposals for new regulations on drug driving. Separate UK and Scottish analyses of the responses were carried out, and the findings presented here are for the Scottish analysis only. These findings will inform decisions about whether Scottish regulations should be brought forward under the Crime and Courts Act 2013 ('the 2013 Act'). Under the 2013 Act, it is for the Scottish Government and Scottish Parliament to decide whether a new drug driving offence should be introduced in Scotland and if so, what the limits for specified drugs should be.

2. Drug driving has been illegal in the UK for many years. However, it has been difficult to prosecute offences under existing legislation because of the need to demonstrate that an individual's driving was impaired as a result of drugs. This is in contrast to the offence of drink-driving, where it has been possible to collect clear evidence of a driver being 'over the limit'. The 2013 Act attempts to overcome this difficulty, by introducing, for the first time, an offence of driving under the influence of a specified drug over a specified limit.

3. To determine which drugs should be included in the legislation, and what the appropriate limits for each drug should be, the UK Government set up an independent expert panel in early 2012 to consider how it will be possible to set levels for the impairing effects of specific drugs on someone driving, and how to measure these levels. The expert panel's report and recommendations were published in March 2013.[1]

4. The UK Government and the Scottish Government then undertook a consultation, setting out three different options for the policy approach to be followed:

    - Option 1 (both Governments' preferred option): took a zero tolerance approach to eight controlled drugs (including LSD) which are mostly associated with illegal drug use, and a road safety risk based approach to eight controlled drugs which have medical uses.
    - Option 2: took the expert panel's recommendations in full – specifying 15 controlled drugs (not including LSD) and setting limits based on evidence of impairment to driving and / or on evidence of increased odds of a road traffic accident, death or injury.
    - Option 3: took a zero tolerance approach to all 15 controlled drugs and LSD.

5. The consultation also sought views on what would be a suitable limit for amphetamine.

About the respondents

6. Forty-three (43) responses were included in the Scottish analysis – 4 from individuals and 39 from organisations. Organisational respondents included: road safety, motoring and licensing organisations; medical, clinical and research bodies; pharmacy groups; alcohol and drug partnerships; and charitable organisations and forums supporting people with chronic pain.

[1] https://www.gov.uk/government/publications/driving-under-the-influence-of-drugs--2

Respondents' views about the policy options

7. Altogether, two-thirds of respondents (28 out of 43) agreed with the Scottish Government's preferred policy approach (option 1). Seven respondents disagreed. The remaining eight respondents either did not state their view, specifically said they had no view, or their view was unclear.

8. Six of the seven respondents who disagreed with the option 1 approach argued instead in favour of the approach set out in option 2, while one respondent expressed a preference for option 3. This latter respondent argued that option 1 did not fully address the significant problem of drug driving and its effect on communities, and felt that option 3 sent out the 'strongest message' that illegal drug use would not be tolerated.

9. Those who were in favour of policy option 1 expressed general support for the proposed zero tolerance approach to the eight illegal controlled drugs – because it 'sends a clear message that you cannot take illegal drugs and drive'. This group also largely expressed their agreement with the distinction made by policy option 1 between the eight illegal drugs and the eight controlled drugs which may be prescribed for legitimate reasons. This group did **not** support policy option 2 because they believed it 'would send out mixed messages' and would cause 'uncertainty' and 'confusion' if higher limits were set for what are already illegal substances.

10. The six respondents who supported option 2 over option 1 expressed the views that policy option 1 was not evidence-based; appeared to be an attempt to tackle drug use rather than dangerous driving; and was inconsistent with the Government's risk-based policy on alcohol. There were also concerns among this group about the likely increased costs associated with the implementation of policy option 1 as compared with option 2.

11. In general, policy option 3 was rejected by respondents as it was considered to have a greater potential for unintended consequences (particularly for those who were taking prescribed medications), and to be too costly.

Views on other issues covered in the consultation

12. Among those respondents who commented, nearly all (22 out of 24) agreed with the Scottish Government's proposal **not** to set limits in urine and nearly three-quarters (23 out of 32) agreed with the proposal to set a zero tolerance limit for cannabis / Sativex.

13. In relation to the question of a limit for amphetamine, there was no clear consensus among respondents about a specific limit. However, a majority of those who commented (10 out of 17) wanted the limit to be **lower** than the expert panel's recommendation of 600 μg/L.

14. Just over one-fifth of respondents (10 out of 43) offered a suggestion about other medications which they thought should be considered in the legislation. These included: other strong opioid drugs prescribed for pain; tricyclic antidepressants and anti-epileptics (also prescribed for pain); legal high salvia and mephedrone and synthetic cannabinoids (increasingly popular among young people); magic mushrooms and certain over-the-counter antihistamines.

Impact assessment

15. Although there was no specific impact assessment produced for Scotland as part of the consultation, a small number of respondents made comments regarding the UK Government's draft impact assessment for England and Wales – related to the estimates of increased prosecutions, decreased casualties and costs. In addition, respondents highlighted possible impacts on a range of businesses and services, including businesses involved in providing training, awareness raising and advice about road safety; healthcare professionals including community pharmacies; the police; the courts; alcohol and drug treatment services; the DVLA; and private companies involved in the manufacture and sale of drug screening devices.

Other comments

16. In addition to their comments on the questions posed in the consultation document, respondents also sometimes made comments that were not directly related to the consultation questions. These addressed a range of issues, including: concerns about implementation of the proposed regulations; the need for raising awareness of the regulations, both among members of the public and among doctors / prescribers; and the need to review procedures for reporting patients to the DVLA when their driving may be impaired as a result of their medical condition or their medication.

1. INTRODUCTION

1.1 This is a report of the findings of a joint public consultation undertaken by the UK Government and the Scottish Government in relation to proposals for new regulations on drug driving limits. The consultation was carried out in 2013 to inform secondary legislation related to the Crime and Courts Act 2013 ('the 2013 Act').

1.2 This report relates to Scottish responses to the consultation and will inform decisions about whether Scottish regulations should be brought forward under the 2013 Act and if so, what policy approach should be adopted for the setting of drug driving limits for specific types of drug. Under the 2013 Act, it is for the Scottish Government and Scottish Parliament to decide whether a new drug driving offence should be introduced in Scotland and if so, what the limits for specified drugs should be.

1.3 Under the Road Traffic Act 1988, it has long been illegal in the UK to drive when impaired by drugs. However, it has been difficult to prosecute offences under this legislation because of the need to demonstrate actual impairment – unlike with drink-driving offences, where it has been possible to collect clear evidence of a driver being 'over the limit'. The 2013 Act is an attempt to overcome this difficulty. It introduces, for the first time, an offence of driving under the influence of a specified drug *over a specified limit*.

1.4 In order to determine which drugs should be included in the legislation, and what the appropriate limits for each drug should be, the UK Government set up an independent expert panel in early 2012 to consider, among other things, how it will be possible to set levels for the impairing effects of specific drugs on someone driving, and how to measure these levels. The expert panel's report, *Driving under the influence of drugs*, was published in March 2013.[2]

1.5 Following publication of the expert panel's report, the UK Government and the Scottish Government then undertook a joint public consultation, setting out three different options for the policy approach to be followed.

1.6 The consultation document was published in July 2013,[3] and a later consultation was carried out in England and Wales specifically in relation to proposed limits for amphetamine. The findings of both these consultations, in relation to England and Wales, were published in March 2014.[4]

1.7 At the Scottish Government's request, the initial (July 2013) consultation was extended to Scotland, and it was agreed that the Scottish responses would be analysed separately by the Scottish Government. This approach would allow the Scottish regulations to take into account the views of people in Scotland and the

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[2] https://www.gov.uk/government/publications/driving-under-the-influence-of-drugs--2

[3] *Regulations to specify the drugs and corresponding limits for the new offence of driving with a specified controlled drug in the body above the specified limit.* Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/229738/consultation-document.pdf

[4] https://www.gov.uk/government/consultations/drug-driving-proposed-regulations

particular context of Scotland's drug strategy. Thus, the consultation analysis report referred to above, does not include an analysis of the Scottish responses.

1.8 On 24 October 2014, regulations were laid before the UK Parliament which specify drug driving limits for 16 different drugs (8 prescription and 8 illicit drugs) in England and Wales. These will come into force on 2 March 2015.

About the consultation

1.9 The consultation document set out three different policy options for the regulatory approach to be followed, and discussed the pros and cons of each option:

- **Option 1:** This was both the Scottish and UK Governments' preferred option. It takes a zero tolerance approach to eight controlled drugs (including LSD) which are mostly associated with illegal drug use, and a road safety risk based approach to eight controlled drugs which have medical uses. In taking a 'zero tolerance approach' to the eight illegal controlled drugs, the Government proposed to set the limits at a level that would not result in prosecution of someone who had consumed a very small amount of the drug in question inadvertently – referred to as the 'lowest accidental exposure limit'). The limits proposed for the other eight controlled drugs that have medical uses are based on recommendations made by the expert panel.
- **Option 2:** Takes the expert panel's recommendations in full – specifying 15 controlled drugs (not including LSD) and setting limits based on evidence of impairment to driving and / or on evidence of increased odds of a road traffic accident and associated deaths and injuries.
- **Option 3:** Takes a zero tolerance approach to all 15 controlled drugs and LSD.

1.10 The limits given in the consultation document for each drug were in microgrammes per litre (μg/L) of blood. Table 1.1 below sets out the Government's proposed limits for the eight illegal and eight prescribed drugs under Option 1.

Table 1.1: Government's proposed limits for eight illegal and eight prescribed drugs

Eight illegal drugs (Zero tolerance approach)			**Eight prescribed drugs (Road safety risk based approach)**	
Benzoylecgonine	50 μg/L		Clonazepam	50 μg/L
Cocaine	10 μg/L		Diazepam	550 μg/L
Delta-9-Tetrahydrocannabinol (Cannabis & Cannabinol)	2 μg/L		Flunitrazepam	300 μg/L
Ketamine	20 μg/L		Lorazepam	100 μg/L
Lysergic Acid Diethylamide (LSD)	1 μg/L		Methadone	500 μg/L
Methamphetamine	10 μg/L		Morphine	80 μg/L
Methylenedioxymethamphetamine (MDMA-Ecstasy)	10 μg/L		Oxazepam	300 μg/L
6-Monoacetylmorphine (Heroin & Diamorphine)	5 μg/L		Temazepam	1,000 μg/L

1.11 The consultation also sought views on what would be a suitable limit for amphetamine which has medical use in specific circumstances, but which is also often taken illegally.

1.12 The consultation contained eight questions. These were:

- 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 at Annex D? For example:
  i. 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).
  ii. Do you have a view on the methodology used to estimate the amount of proceedings? If so please give your reason(s).
  iii. Do you have a view on the methodology used to estimate the drug driving casualties baseline? If so please give your reason(s)
  iv. Do you have a view on the methodology used to estimate the casualty savings? If so please give your reason(s).
  v. 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).

1.13 The consultation document was sent directly to 64 organisations based in England and Wales, many of which have a national remit. In addition, 67 organisations in Scotland were invited to take part in the consultation.

1.14 The UK Government also organised a briefing session in July 2013 in London and invited stakeholders to attend this session for further information. In Scotland, information about the consultation was put on the Scottish Government website and a news release was issued to help raise awareness of the consultation.

2. THE CONSULTATION RESPONSES AND RESPONDENTS

How the responses were received

2.1 All responses to the consultation were received by the UK Government. The majority were sent by email. As noted above, the UK Government undertook its own analysis of the responses (which did not include the Scottish responses). The UK Government then forwarded to the Scottish Government all responses from organisations with a UK-wide remit, and all responses from organisations and individuals in Scotland.

Number of responses received

2.2 Forty-three (43) responses were included in the Scottish analysis. These comprised 4 responses from individuals and 39 from organisations. Altogether, 22 responses came from Scotland-based respondents and 20 from organisations based outside of Scotland but with a UK-wide remit. In addition, there was one respondent from Europe. (See Table 2.1.)

Table 2.1: Geographical location of respondents

	Individual		Organisation		Total	
	n	**%**	**n**	**%**	**n**	**%**
Scotland	4	100%	18	46%	22	51%
UK-wide	–	0%	20	51%	20	47%
Europe	–	0%	1	3%	1	2%
Total	**4**	**100%**	**39**	**100%**	**43**	**100%**

Percentages do not all total 100 due to rounding.

2.3 The organisational respondents included road safety, motoring and licensing agencies; medical, clinical and research bodies; pharmacist groups and pharmaceutical bodies; alcohol and drug partnerships; and charitable organisations and forums supporting patients with chronic pain. (See Table 2.2.)

Table 2.2: Organisational respondents

Type of organisational respondent	**n**	**%**
Road safety, motoring and licensing organisations	8	21%
Medical, clinical and research bodies	7	18%
Pharmacist groups and pharmaceutical bodies	6	15%
Alcohol and drug partnerships	5	13%
Charitable organisations and forums supporting patients with chronic pain	5	13%
Other public sector organisations	4	10%
Private sector organisations	3	8%
Other organisational respondents	1	3%
Total	**39**	**100%**

Percentages do not total 100 due to rounding.

2.4 In relation to the four individual respondents, one of these identified himself as a consultant psychiatrist, and another as a roads policing officer. For the purposes of comparative analysis, the first of these respondents has been grouped with the medical, clinical and research bodies and the second with the road safety, motoring and licensing organisations. The other two individuals have been grouped with 'other' organisational respondents.

Approach to the analysis

2.5 The analysis presented in this report is qualitative in nature – that is, the aim has been to identify the main themes raised by respondents in their free text comments. Since these comments were made spontaneously, it is not ordinarily appropriate to report counts for the different themes raised. However, given the relatively small number of responses to this consultation, if a significant issue was made by just one or two respondents, this is generally stated.

2.6 Several of the consultation questions took the form of a yes / no question; however, no formal consultation questionnaire or tick boxes were provided for respondents to indicate their agreement / disagreement. In questions where respondents were asked if they agreed with the Government's proposals, 'yes / no' responses have been **imputed** on the basis of an analysis of the respondents' comments. If it was not clear from the respondent's comments whether they agreed or disagreed with the proposal, their response was coded as 'unclear' or 'neither agree nor disagree'. Throughout this report, the figures shown in tables are therefore based on these imputed responses.

2.7 Note that not all respondents answered all questions. Annex 2 contains information about the number of responses received for all questions.

2.8 Respondents also frequently made comments in relation to the consultation proposals which did not relate specifically to any of the consultation questions. These comments have been analysed separately to identify the main themes contained within them. This analysis will be presented in the last chapter of this report.

3. VIEWS ABOUT THE THREE POLICY OPTIONS (Q1 AND Q2)

3.1 The first two questions in the consultation asked about respondents' agreement (or disagreement) with the Government's preferred policy option 1, and their views about policy options 2 and 3. The first two questions were:

> **Question 1:** Do you agree with the Government's proposed approach as set out in policy option 1? If not, please provide your reason(s).
>
> **Question 2:** Do you have any views on the alternative approaches as set out in policy option 2 and 3?

3.2 There was a great deal of overlap in relation to the comments made at Questions 1 and 2. Therefore, the analysis of these two questions was carried out in tandem, and the findings are discussed together in this section.

3.3 All 43 respondents made a comment at Question 1, and 33 respondents (30 organisations and 3 individuals) made a comment at Question 2.

3.4 Respondents' agreement or disagreement with the option 1 approach has been inferred from their comments, and Table 3.1 below shows the results. (As Question 2 did not ask respondents if they agreed or disagreed with policy options 2 and 3, no table has been produced for this question.)

3.5 In total, 28 of the 43 respondents (65%) agreed with the Government's preferred policy approach (option 1). Seven (16%) disagreed, and in eight responses, the respondent either did not state their view, specifically said they had no view, or their view was unclear.

Table 3.1: Question 1 – Do you agree with the Government's proposed approach as set out in policy option 1?

Respondent type	Yes		No		Neither agree nor disagree, or unclear		Total	
Road safety, motoring and licensing	8	89%	–	0%	1	11%	9	100%
Medical, clinical and research	2	25%	3	38%	3	38%	8	100%
Pharmacist groups and pharmaceutical bodies	6	100%	–	0%	–	0%	6	100%
Alcohol and drug partnerships	3	60%	2	40%	–	0%	5	100%
Charitable organisations and forums supporting patients with chronic pain	2	40%	–	0%	3	60%	5	100%
Other public sector organisations	3	75%	–	0%	1	25%	4	100%
Private sector organisations	3	100%	–	0%	–	0%	3	100%
Other respondents	1	33%	2	67%	–	0%	3	100%
Totals	**28**	**65%**	**7**	**16%**	**8**	**19%**	**43**	**100%**

Percentages do not all total 100 due to rounding.

3.6 Among the seven respondents who disagreed with the approach set out in option 1 were three medical, clinical and research agencies; two alcohol and drug partnerships; and two individuals. Six of the seven respondents who disagreed with the option 1 approach argued instead in favour of (or implied they were in favour of) the approach set out in option 2, while one respondent expressed a preference for option 3.

3.7 In general, irrespective of whether respondents favoured policy options 1, 2 or 3, they were supportive of the Government's attempt to tackle the problem of drug driving to improve road safety. Some also commented on the positive benefits of the legislation in terms of reducing the amount of time, expense and effort involved for the police and courts when prosecutions fail because of an inability to prove that the driver was impaired by a particular drug.

Respondents' reasons for supporting policy option 1

3.8 The 65% of respondents who were in favour of policy option 1 described it as 'the most appropriate approach', and a 'sensible' and 'pragmatic' solution. It was common for this group to explicitly state that they were in favour of a zero tolerance approach to the eight illegal controlled drugs – because it 'sends a clear message that you cannot take illegal drugs and drive'. Some respondents commented that this approach was consistent with the Government's wider drug strategy, and suggested that it might help to create an environment that would discourage people from taking drugs. One respondent (a road safety / motoring organisation) cited evidence in support of their view from an AA Populus poll which showed that 73% of drivers believe that drivers should be prosecuted if they have traces of illegal drugs in their blood, even if these are not impairing their driving.

3.9 This group also generally expressed their agreement with the distinction made by policy option 1 between the eight illegal drugs and the eight controlled drugs which may be prescribed for legitimate reasons. These respondents largely supported an impairment-based approach for drivers taking prescribed medication as 'fair', and 'the best way forward', and suggested that a zero tolerance approach to prescribed medication might discourage patients from taking their medication – which could have negative consequences, not only for their health and wellbeing, but also for their driving.

3.10 In their comments at Question 2, this group generally stated that they did **not** support policy option 2 because they believed it 'would send out mixed messages' (or 'the wrong message') and would cause 'uncertainty' and 'confusion' if higher limits were set for what are already illegal substances. A small number of respondents who stated their support for policy option 1 nevertheless expressed some reservations about having higher risk-based limits for the eight controlled drugs which may be prescribed. While these respondents specifically stated that they supported policy option 1, they also thought that policy option 3 was preferable to option 2, as option 3 'sends out the strongest message'.

3.11 A small number of those who supported policy option 1 noted that the consultation document estimated net costs to the justice system as higher for this option than for option 2. However, these respondents argued that these additional costs would be outweighed by the significant benefits to society of greater safety on the roads. One respondent with a road safety remit suggested that if the new legislation included provision for an offender's vehicle to be seized upon their conviction, the additional costs associated with option 1 could be offset by the proceeds of sales or scrappage.

Respondents' reasons for NOT supporting policy option 1

3.12 As shown in Table 3.1 above, seven respondents (16% of all respondents) were not in favour of policy option 1. One of these, an alcohol and drug partnership, stated a preference for option 3, saying that 'option 1 fails to fully address the significant problem drug driving creates in our communities,' and 'option 3 sends the strongest message and confirms you cannot take illegal drugs and drive'.

3.13 However, of those who did not support policy option 1, most (6 out of 7) supported (or implied that they supported) option 2 instead. This group expressed the views that policy option 1:

- Sought to 'persecute' people who had taken a particular drug, irrespective of whether it makes them a danger on the road
- Was inconsistent with the Government's risk-based policy on alcohol, which allows people to drink within a specific limit and still be able to drive[5]
- Was not evidence-based, since there is no evidence that the approach proposed in option 1 would actually alter behaviour
- Appeared to be an attempt to tackle drug use, rather than dangerous driving caused by drug use; thus it was considered an inappropriate use of the Road Traffic Act
- Was illogical, as it suggests the Government believes that driving with eight illicit drugs in the body is more serious than driving with alcohol, or any other legal high in the body. Moreover, there are a number of common prescribed medicines which are not controlled, which can also impair driving, but which have not been included.

3.14 The point was made by one respondent from a medical / clinical organisation that it was unclear upon what basis the police could demand a blood sample, if an individual's driving were not impaired in some way. Another respondent – an alcohol and drug partnership – argued that there should be a requirement within the regulations, not **only** to measure drug levels in the blood, but **also** to provide evidence of impairment and ability to drive.

3.15 It was noted that policy option 1 was expected to result in an estimated 3,100 **more** proceedings than option 2 – and that these proceedings would likely be against people

[5] Note that at the time this consultation took place in 2013, the drink drive limits in Scotland and England were the same: 80 milligrammes of alcohol per 100 millilitres of blood; 35 microgrammes per 100 millilitres of breath; or 107 milligrammes per 100 millilitres of urine. However, from 5 December 2014, the Scottish Government reduced the drink drive limit in Scotland to: 50 milligrams of alcohol in every 100 millilitres of blood; 22 micrograms of alcohol per 100 millilitres of breath; or 67 milligrammes per 100 millilitres of urine – bringing the limits in Scotland in line with most other European countries.

who had been stopped by the police with certain levels of illicit drugs in their bodies below the threshold for impairment. The view was expressed that it was not clear how these prosecutions would be in the public interest. Moreover, they would result in a net cost, while policy option 2 would result in a net benefit, with the difference around £32m.

Unclear responses

3.16 Table 3.1 above shows that eight respondents (19%) either expressed no views about the policy options, or expressed unclear views. One of these, a road safety organisation, specifically stated that they could not come to a view because of insufficient information provided within the consultation document. Most of the others did not address the question, but rather raised issues or concerns about implementation (discussed below).

Reasons for NOT supporting policy option 3

3.17 The reasons that respondents tended to support policy option 1 over option 2 are explained above. However, in their comments at Question 2, respondents also (apart from a few exceptions) generally endorsed the arguments made in the consultation document that option 3 should **not** be pursued. This option was considered to have a greater potential for unintended consequences (particularly for those who were taking prescribed medications), and to be too costly.

Other issues raised

3.18 In their comments on Questions 1 and 2 respondents raised a wide range of other issues. Many of these concerned the proposed levels for one or more specific drug(s). Other comments focused on implementation or enforcement issues. The following is a summary of the points made:

- Respondents often raised the issue of opiate tolerance. The point was made that there is a complex relationship between individual metabolism, tolerance to opiates and interactions with other medication, which may affect blood levels, but not always result in impairment. The issue of tolerance was also highlighted by other respondents specifically in relation to their comments about methadone and morphine limits (discussed below).
- While respondents generally welcomed the provision of a medical defence for people using controlled drugs legitimately through prescription, others expressed concerns that this proposal would put an unfair burden of proof upon the person accused of committing an offence, and this could cause considerable stress to people who may already be seriously ill.
- One respondent, from the police, noted that current operational procedures involve testing for alcohol first. Where a positive test is obtained for alcohol, no further testing is carried out for drug use, as it is more efficient to pursue a prosecution for drink driving. The point was made that the introduction of the proposed regulations is unlikely to alter these arrangements in any significant way, and so the number of prosecutions for drug driving offences is likely to remain at a relatively low level compared to prosecutions for drink driving. Another respondent, from a road safety organisation, described these current procedures as ‘unacceptable’, and called for

the drug driving offence to also be taken into account (as a second offence) in the prosecution and sentencing of offenders.

- Some respondents highlighted the need to publicise and raise awareness among drivers of the proposed changes in legislation. Media campaigns, including campaigns involving young people, were suggested. In addition, respondents frequently emphasised the importance of raising awareness among medical professionals (doctors and pharmacists, in particular) about their role in alerting patients of the changes in legislation. There were also calls for improvements to current procedures regarding notification to the DVLA of a patient's medical condition and / or medication. The point was made (often by organisations involved in road safety / motoring) that current procedures rely upon the patient to self-report, and in the view of these respondents, this was not working well.

Comments about, or concerns expressed, about the proposed limits for specific drugs

3.19 Respondents expressed a range of comments about the proposed levels set for specific drugs (or about whether certain drugs should be in the zero tolerance category, or the risk-based category). Views from different respondents were sometimes contradictory.[6]

- **LSD:** Eight respondents made comments about the proposal to include LSD in the list of illegal drugs for which zero tolerance limits would be set. This proposal was contrary to the recommendations of the expert panel, who argued that LSD should not be included in the regulations as current use of LSD in the UK is not high and no data were available to enable the panel to propose a limit.

  Of the eight respondents who made a comment about LSD, six argued that LSD should be included in the regulations since its omission could result in the 'misleading message that use of LSD is permissible when driving'. One of the respondents, from a medical / clinical body, endorsed the expert panel's recommendation that LSD should be omitted. This respondent also offered the alternative of setting a 'threshold limit' (rather than a zero tolerance limit) for LSD, and suggested that this might be able to be derived on the basis of the minimal evidence that does exist. The eighth and final respondent was from a private sector organisation involved in the development and sale of devices used for drug screening. This respondent echoed the expert panel's conclusions that the use of LSD is incompatible with driving, and that there is currently no demand (globally) for an LSD drug screen.

- **Ketamine:** Ten respondents made a comment in relation to ketamine. Most made the point that, although ketamine is mainly used for medical purposes as an anaesthetic, it is also sometimes prescribed to patients for severe neuropathic pain. It was suggested that current data on ketamine was likely to underestimate the actual number of prescriptions issued, since ketamine is often prescribed by

[6] This discussion incorporates comments made at Question 6 which related to the drugs proposed for inclusion in the regulations.

specialist NHS services from secondary care, or from hospices or other non-NHS palliative care services. Respondents thought that the proposed limit for ketamine could result in people being arrested unfairly, although the point was also made that these individuals would still be able to rely upon a medical defence. There was disagreement about whether the proposed zero tolerance limit for ketamine should be raised to take into account its legitimate use. One road safety / motoring / licensing agency suggested it could be raised, while a medical / clinical / research body emphasised that there is robust evidence that use of the drug causes driving impairment. This latter respondent supported the zero tolerance limit and argued that prescribers should advise patients **not** to drive when taking ketamine.

- **Morphine and diamorphine:** Twelve respondents made comments in relation to morphine or diamorphine. Six respondents noted that legitimate doses for prescribed morphine may vary widely, and there may be considerable variability in the way morphine at different doses affects a patient's ability to drive. The point was also made that there is a range of different formulations of morphine available, and that driving may be more impaired if the total dose is taken as an immediate release tablet or oral solution. Modified release preparations may produce a relatively constant blood concentration.

  Other respondents expressed concerns that, apart from morphine, limits had not been specified for other opioid drugs which are often also commonly prescribed for pain relief. (These concerns will be discussed in Section 7 in relation to other medications which may need to be considered by the regulations.)

- **Methadone:** Seven respondents made comments about methadone, and these generally highlighted the use of methadone in the treatment of drug addiction. Three respondents made the point that prescribed doses of methadone may vary widely, depending on a person's history and their tolerance. Use of methadone, even at a very high level, may be safe and not render an individual unfit to drive. However, one respondent argued for a lower limit for methadone, given the frequency of methadone misuse.

- **Cannabis:** Six respondents made comments about cannabis. In general, respondents commented that current evidence suggests that cannabis use alone is less likely than alcohol to result in impairment of driving, or a fatal accident. However, one respondent cited research that suggested that cannabis used **in conjunction** with alcohol caused significantly greater impairment. One medical / clinical organisation made the point that there is a potential for unfairness in relation to cannabis. In particular, metabolites of cannabis may be detected in the body for several days after use, without any adverse impact on driving. This could result in someone who has used cannabis legally in countries where its use is permitted falling foul of the UK legislation days later.

- **Cocaine:** Three respondents made comments about cocaine. One noted that, although very rare, cocaine can be used as a legitimate ingredient in some ophthalmological preparations, and also for packing the nose in extreme cases of nasal blood loss. Another queried whether there would be any implications for people working with controlled substances in a laboratory context, and whether

laboratory work could be legitimately used as a defence (for example, there may be cases where drugs analysts have raised levels of benzoylecgonine in their blood, although they have not consumed cocaine). The third respondent suggested that the limits for cocaine and benzoylecgonine should be set at the same level, since these levels vary inversely according to the time that has elapsed since a person has taken cocaine. Drug screening has reportedly shown that when cocaine levels are high, benzoylecgonine levels are low, and vice-versa.

- **Dihydrocodeine:** Two respondents queried statements in the consultation document (paragraph 14.16) which said that dihydrocodeine is metabolised to morphine, and therefore a single morphine limit would be sufficient to detect use of morphine itself, dihydrocodeine and codeine. These respondents believed that dihydrocodeine was **not** metabolised to morphine, but rather to dihydromorphine. They queried whether dihydromorphine would be detected through morphine screening.

3.20 Several respondents commented on the perceived disparity between the Government's approach to alcohol and the preferred option 1 approach. While some thought this approach was appropriate, given that alcohol is not an illegal drug, others thought that it was illogical to propose a zero tolerance of drugs such as cannabis, which do not necessarily cause impairment to driving when taken at low levels, while at the same time taking a risk-based approach to alcohol.

4. PROPOSAL NOT TO SET SPECIFIED LIMITS IN URINE (Q3)

4.1 The consultation document explained that, on the basis of the expert panel's recommendation, the Government proposed **not** to set limits in urine for drugs covered under the new offence. The reason given was that it is not possible to establish evidence-based concentrations of drugs in urine. There is also no translation of the concentration of a drug in blood to a concentration of that drug in urine. Respondents were asked to give their views about this proposal, and Question 3 asked:

> **Question 3:** 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?

4.2 Altogether 24 respondents (23 organisations and 1 individual) replied to Question 3. Of these, 22 out of 24 (92%) agreed with the Government's proposal **not** to set limits in urine. None of the respondents disagreed with this proposal; however, two of the 24 (8%) expressed views that were unclear. See Table 4.1.

Table 4.1: Question 3: Do you agree with the proposal not to set specified limits in urine?

Respondent type	Yes		No		Unclear		Total	
Road safety, motoring and licensing organisations	6	100%	–	0%	–	0%	6	100%
Medical, clinical and research	3	75%	–	0%	1	25%	4	100%
Pharmacist groups and pharmaceutical bodies	5	100%	–	0%	–	0%	5	100%
Alcohol and drug partnerships	3	75%	–	0%	1	25%	4	100%
Charitable organisations and forums supporting patients with chronic pain	1	100%	–	0%	–	0%	1	100%
Other public sector organisations	2	100%	–	0%	–	0%	2	100%
Private sector organisations	2	100%	–	0%	–	0%	2	100%
Other respondents	–	0%	–	0%	–	0%	0	100%
Totals	**22**	**92%**	–	**0%**	**2**	**8%**	**24**	**100%**

4.3 In general, respondents said that they were happy to be guided by the recommendations of the expert panel in this matter. Some said that they considered it to be 'sensible' not to set limits in urine given the arguments set out in the consultation

document. One respondent endorsed these arguments, stating that, ‘the concentration of a drug and / or its metabolites in urine varies more than in plasma and oral fluid’.

4.4 A small number of points were raised by respondents in their comments on Question 3. These issues were raised both by those who agreed with the proposal, and those who expressed unclear views.

4.5 One respondent voiced the view that the Government’s arguments were inconsistent – sometimes based on evidence (for example, in the case of not setting limits in urine) and at other times based on current policy (in relation to setting zero tolerance limits for certain drugs). Others highlighted concerns about the practical aspects of enforcement:

- One respondent (from the police) expressed the view that the lack of an alternative to testing in blood is a weakness in the process. The point was made that some individuals may be unable to provide a blood sample – either because of a diagnosed medical condition, or because of a fear of needles. Without a blood sample, there will be no way to take forward prosecution under the proposed new regulations. Therefore, existing procedures related to the Road Traffic Act 1988 (section 4) will have to come into play. This respondent believed that effective enforcement would require an alternative to taking blood.
- One respondent (an alcohol and drug partnership) also had concerns about the practical implications of enforcement, and argued that ‘impairment and driver responsibility should take precedence over any specified limits directed by legislation’.

4.6 Finally, one respondent (from a medical / clinical background) explicitly stated that they had no view on the question of whether limits should be set in urine. However, this respondent noted that urine testing for drugs is currently an established part of the current road traffic process and suggested that it should be continued.

5. VIEWS ABOUT THE LIMIT FOR CANNABIS / SATIVEX (Q4)

5.1 The consultation document discussed a proposed limit for cannabis. The point was made that around 1,500 people in the UK are currently prescribed Sativex (a cannabis plant-based drug licensed for medical use in the UK in the treatment of multiple sclerosis (MS)), and around 200 of these may be driving. Roadside screening tests are unable to distinguish between cannabis and Sativex.

5.2 MS is a medical condition that must be notified to the DVLA. If a patient's doctor provides an opinion to the DVLA that the patient is safe to drive, then the DVLA would notify the patient that a short-term driving licence will be issued for up to three years. Along with this notification, the DVLA proposes to include advice to drivers that if they have any involvement with the police related to their driving, they must be able to provide evidence that they have been prescribed Sativex. The DVLA also proposes to contact the Association of Chief Police Officers (ACPO) to make them aware of the situation with respect to the use of Sativex in the treatment of MS.

5.3 Given the very small number of drivers using prescribed Sativex, and the more prevalent use of illegal cannabis, the Government proposed to take a zero tolerance approach to the use of cannabis. Respondents were asked for their views:

> **Question 4:** 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?

5.4 Altogether, 32 respondents (29 organisations and 3 individuals) made a comment relevant to Question 4. Of these, 23 (72%) agreed with the approach proposed by the Government regarding the limit for cannabis and four (13%) disagreed. Five other respondents (16%) made comments which did not express a clear view. See Table 5.1.

Table 5.1: Question 4: Is the approach we are proposing to take when specifying a limit for cannabis reasonable for those being prescribed Sativex?

Respondent type	Yes		No		Unclear		Total	
Road safety, motoring and licensing	7	88%	1	13%	–	0%	8	100%
Medical, clinical and research	2	33%	1	17%	3	50%	6	100%
Pharmacist groups and pharmaceutical bodies	5	100%	–	0%	–	0%	5	100%
Alcohol and drug partnerships	3	75%	–	0%	1	25%	4	100%
Charitable organisations and forums supporting patients with chronic pain	1	50%	–	0%	1	50%	2	100%
Other public sector organisations	2	100%	–	0%	–	0%	2	100%
Private sector organisations	3	100%	–	0%	–	0%	3	100%
Other respondents	–	0%	2	100%	–	0%	2	100%
Totals	**23**	**72%**	**4**	**13%**	**5**	**16%**	**32**	**100%**

Percentages do not all total 100 due to rounding.

Reasons for agreeing with the proposed approach

5.5 Among those 23 respondents who agreed with the proposed approach regarding cannabis and Sativex, some gave no reason. However, others described the proposal as 'reasonable', 'pragmatic' and 'proportionate', since the use of prescribed Sativex is rare, while the illegal use of cannabis is much more common.

5.6 One private sector respondent described the concern about prescribed Sativex as 'a red herring', claiming that there were only a very small number of MS sufferers taking prescribed Sativex, and many of these are unable to drive as a result of their illness. However, others emphasised that the police should be made aware that people with MS who are taking Sativex may be driving legally.

Reasons for disagreeing with the proposed approach

5.7 Four respondents disagreed with the proposed approach, and these offered lengthier and more complex comments. The reasons for disagreeing with the proposed zero tolerance approach to cannabis / Sativex were as follows:

- The proposal was considered to be inconsistent with the Government's own arguments for **not** pursuing Policy Option 3. In particular, the consultation document acknowledges that the use of psychoactive drugs may improve driving for some patients (resulting in freedom from pain and a greater degree of mobility). It was felt that these same arguments should apply to the use of Sativex for therapeutic purposes.
- It was thought that the proposed zero tolerance approach towards cannabis / Sativex would cause unintended harm by preventing some patients from receiving treatment that minimises their symptoms (on the one hand), and by causing nuisance to those who wish to persist with Sativex (on the other). Although respondents acknowledged that the use of Sativex is currently very low in the UK, it was thought that there is likely to be a growing acceptance and use of cannabis-based medicines over the next few years. One respondent noted that there are ongoing clinical trials related to the use of Sativex for relief of acute and severe pain in patients with ulcers, diabetes and terminal cancer.
- It was argued that this proposal represented an intention by the Government to shape evidence to fit policy, whereas those who disagreed with this proposal thought that policy should be shaped by evidence.
- The view from one road safety organisation was not entirely clear; however, this respondent appeared to be arguing for a stronger, more robust stance regarding prescribed Sativex than that proposed by the Government. This respondent made the point that Sativex is currently used as a 'last resort' to control spasticity among MS sufferers, and that MS causes a variety of symptoms which would make an individual unfit to drive. This respondent thought there should be no defence in law for patients who ignore medical advice about their prescribed medication and its effects on driving.

Other comments made by respondents

5.8 The comments of five respondents were unclear in relation to whether they agreed or disagreed with the proposed approach to cannabis / Sativex. In general, these respondents expressed concerns about the approach, but without explicitly stating whether they agreed or disagreed with it. The main concern was that people with MS and other painful conditions should be able to benefit from Sativex and to continue to use it without fear of arrest or prosecution. These respondents thought it would be distressing for people who are ill to be put in the position of having to defend their use of prescribed medication. One respondent from a charitable organisation involved in supporting people with chronic pain suggested that a central register could be set up which contains the names and addresses of all patients receiving Sativex under prescription, and that this database could be available to the police.

5.9 Respondents who were in favour of the proposal to take a zero tolerance approach to cannabis / Sativex expressed different concerns, and these were mainly about current procedures for warning patients about the dangers of driving when taking certain prescribed medications, and the procedures for notifying the DVLA about patients taking such medications. Respondents often expressed the view that any changes in legislation would need to be accompanied by clear information for prescribers, pharmacists and patients. Moreover, respondents wanted prescribers and pharmacists to take more responsibility in making patients aware of the potential risks, but also thought that people who ignore these warnings should not be able to claim a medical defence.

5.10 Some respondents supported the proposal, discussed in the consultation document (paragraph 14.20), that the DVLA notifies all drivers being prescribed Sativex to give them information about the changes to legislation.

6. VIEWS ON A LIMIT FOR AMPHETAMINE (Q5)

6.1 The consultation document discussed options for a drug driving limit for amphetamine. The point was made that amphetamine has some medical use in specific circumstances. In particular, it is often used to treat Attention Deficit Hyperactivity Disorder (ADHD) among children and adolescents, and its use among adults diagnosed with ADHD is becoming more common. However, amphetamine (and drugs containing it) are also frequently used illicitly.

6.2 The consultation document noted that adult ADHD is a developing branch of medicine, and there is currently a lack of evidence upon which to determine the road safety risk of prescribed drugs containing amphetamine on drivers with ADHD, or the appropriate blood threshold limits for adults taking prescribed medications containing amphetamine.

6.3 The expert panel had recommended a limit of 600 μg/L. However, upon publication of their report *'Driving under the influence of drugs'*, the UK Government had received comments on the report which suggested this limit was too high. Another expert group had proposed a limit of 100 μg/L (which would be above the standard dosage for most people being treated for ADHD). Another suggestion was that the limit should be set at 50 μg/L, which is the same as that in France and the Netherlands.

6.4 The consultation asked for comments on the limit for amphetamine, and Question 5 asked:

> **Question 5:** Do you have a view as to what limit to set for amphetamine? If so please give your reason(s).

6.5 Altogether 20 of the 43 respondents (19 organisations and 1 individual) made a comment at Question 5. Of these, 17 offered a view about what the drug driving limit for amphetamine should be. As Table 6.1 shows, there was no clear consensus about a specific limit. However, it would appear that the majority (10 out of 17) wanted the limit to be set **lower** than the expert panel's recommendation of 600 μg/L.

Table 6.1: Respondents' views about the limit for amphetamine

Limit preferred by respondents	Number of respondents
Zero tolerance	3
50 μg/L	3
100 μg/L	4
600 μg/L	4
Unspecified limit	3
Total	**17**

6.6 As Table 6.1 shows, three respondents did not state a preference for a specific limit, but rather made more general statements about the limit. For example: 'There should

be a limit set for amphetamine' (as it can adversely affect an individual's ability to drive); 'Amphetamine should have a limit rather than a zero tolerance limit' (because of its use in the treatment of ADHD and substance misuse); and 'Any limit set should be at the lower end of advice given by [the] expert panel'.

6.7 It is not clear from the comments made by those who wanted a 'zero tolerance' limit what they understood 'zero tolerance' to mean, and whether it was intended to mean a 'lowest accidental exposure limit' as discussed in the consultation document.

6.8 The largest group of respondents commenting on this question were those with an interest in road safety, motoring and licensing. Altogether, seven of the 17 respondents who made a comment regarding a possible limit for amphetamine were in this category. Three of the seven were in favour of the expert panel's recommended limit of 600 μg/L, two preferred a limit of 100 μg/L, and two wanted a 'zero tolerance' approach to be taken.

6.9 Respondents' arguments in favour of a particular limit were as follows:

- **50 μg/L:** This limit was seen to be consistent with that in other European countries.
- **100 μg/L:** It was argued that this limit would be above the therapeutic dose of amphetamine (for people taking the drug legitimately), but it would allow the larger group of people who are taking the drug illegally to be identified. There was a view that a higher limit (for example, 600 μg/L) would fail to identify many people taking amphetamine illegally.
- **600 μg/L:** This limit was seen to be consistent with the arrangements proposed by the Government for the eight other controlled drugs which can be taken legally under prescription. Respondents argued that the limit should be set at the point at which driving is likely to be impaired; and that, without evidence of impairment, there was 'no reasonable basis for setting a lower limit'. One respondent, commenting on the point made in the consultation document – that some people felt the expert panel's recommendation of 600 μg/L was too high – said that the reasons for choosing this limit were explained clearly in the expert panel's report, while those who objected to this limit provided no counter-arguments – except to say that it seems too high. The point was made that setting a lower limit would result in higher costs, including higher costs to the taxpayer from pursuing additional prosecutions.
- **Zero tolerance:** A 'zero tolerance' approach was considered to be appropriate for amphetamine because 'amphetamine is an illegal drug', and because the number of adults taking amphetamine on prescription is very small. The point was made that if an adult taking amphetamine had been assessed as competent to drive, they should simply carry their repeat prescription with them so that it can be used as a medical defence.

6.10 Two respondents suggested that the Government should seek further information before deciding upon a limit. One respondent in favour of the proposed 50μg/L limit suggested that the Government should find out why other European countries have

set the limit for amphetamine at this lower level. A second respondent thought that further information should be obtained about ‘the mean therapeutic dose for adults taking ADHD medications’ before a limit was set.

6.11 Other issues highlighted by respondents were as follows:

- Amphetamine is also used for the treatment of hypersomnia and narcolepsy in adults, and these conditions should be considered in the setting of limits, and in terms of an allowable medical defence.
- After heroin, amphetamine was reported to be one of the most commonly injected street drugs in the UK.
- Amphetamine was reported to have a short half-life, and therefore it would be important for a blood test to be undertaken quickly to secure a conviction for drug driving.
- The DVLA should be notified about patients being prescribed amphetamine.
- It was noted that the first-line treatment for ADHD is methylphenidate (Ritalin), which would not be identified in an amphetamine saliva screen. The point was made that dexamphetamine was an alternative treatment, and that this is not the same as amphetamine. There was a query about whether dexamphetamine would be identified through amphetamine drug screening.

7. OTHER MEDICATIONS WHICH SHOULD BE CONSIDERED (Q6)

7.1 The consultation document asked whether there were any other medicines which should be considered by the regulations. Question 6 asked:

> **Question 6:** 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).

7.2 Altogether 22 of the total 43 respondents (all organisations) made a comment that was relevant to Question 6. As this was not an 'agree / disagree' question, no summary table is provided.

7.3 Twelve of the 22 respondents simply stated that they either were not aware of any other medicines that should be taken into account by the 'lowest accidental exposure limit', or they said they felt unable to comment on the question.

7.4 However, the other 10 respondents offered suggestions about additional medicines which they believed should be considered in the legislation.[7] The respondents who made more substantive comments were mainly from medical, clinical or research bodies, from pharmacy groups, or from charities that support people living with chronic pain.

7.5 Respondents commented that there are a range of medications, including a number of over-the-counter medications, which can affect driving ability. In addition, respondents identified other controlled drugs, non-controlled drugs frequently prescribed for pain relief, and so-called 'legal highs', which they suggested should be considered for inclusion in any regulations. Those mentioned specifically (and the comments respondents made about them) were:

- Buprenorphine, oxycodone, fentanyl, tramadol (opioids sometimes prescribed for pain relief)
- Anti-epileptics and tricyclic antidepressants (both used for pain relief and also often misused)
- Legal high salvia and mephedrone (increasingly popular among young people)
- Synthetic cannabinoids (increasingly used by young people to avoid detection in drug tests; some have a higher potential for harm than cannabis itself)
- Magic mushrooms (have similar intoxicating effects to LSD, and the prevalence of use is also similar to LSD)
- Antihistamines (can be purchased over-the-counter; some can cause drowsiness, and so affect driving ability).

7.6 The point was made that it is often a **combination** of drugs (or a combination of drugs and alcohol, either above or below the legal limits) that can cause impairment. It was

[7] Some respondents who commented at Question 6 queried the limits proposed for specific drugs. These comments have been discussed in relation to Questions 1 and 2 and are not repeated here.

suggested that this may present difficulties when attempting to identify any single drug above a specified limit for the purposes of prosecution.

Concerns about unintended consequences

7.7 Several respondents made the point that morphine is the main strong opioid drug used in the treatment of severe pain, and that there is no evidence that any other opioid drug provides more effective analgesia. However, this group of respondents believed that if morphine was the only opioid drug included in the list of prescribed drugs, there may be pressure from patients on prescribers to begin prescribing alternative opioids (including oxycodone, fentanyl and buprenorphine), which would not be detected by screening. It was felt that some patients may not feel reassured that they have a medical defence in relation to prescribed morphine; and that they may prefer to be prescribed a drug which would not put them at risk of arrest. The point was made that this would have significant implications for prescribing costs to the NHS. One respondent queried whether the proposals had been discussed with the Health Department.

7.8 It was thought that the change in legislation might also result in illicit opiate users switching to other opiates in order to continue to drive without risk of arrest.

Respondents' further suggestions

7.9 Comments on this question included a suggestion that further pharmacological and epidemiological data should be gathered so that dose equivalents associated with impairment for other strong opioids could be derived and made available for drug-detection purposes. As an interim measure, it was suggested that scientists and clinicians could agree dose equivalents for all strong opioids based on their analgesic efficacy, as these data are already available. This would allow prescribers to alert patients when their drug regimen is likely to be impairing.

7.10 Several respondents also suggested that procedures should be reviewed and may need to be improved in relation to: (i) prescribers alerting patients about the effects of their medication on driving; and (ii) notifying the DVLA about patients whose medical condition or prescription may impair their driving. One respondent, a road safety organisation, commented that some patient information leaflets for stronger opiate medications state clearly that the patient should not drive when taking these medications. However, the leaflets for less strong medications state: 'do not drive if affected', thus leaving the decision to the discretion of the patient. This issue may need to be addressed with drug manufacturers.

7.11 A respondent from the police suggested that the police could assist in providing data from drug test results, which would help to identify the drugs most commonly detected in drivers over the last five years.

8. IMPACT ASSESSMENT (Q7 AND Q8)

8.1 Annex D of the consultation document contained a lengthy and detailed analysis of evidence used as the basis for an impact assessment conducted by the UK Government into the likely effects of the new offence on costs for businesses, the third sector and the public sector. The impact assessment focused on estimating the likely changes in the number of proceedings and reductions in the number of casualties which may result from the introduction of the new regulations and associated costs.

8.2 Question 7 in the consultation document asked a series of questions about the methodology used in making these estimates, and invited respondents to provide additional evidence that they may be aware of. Question 8 asked businesses for their views about whether the proposals would have any impact on them.

Question 7: 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 at Annex D? For example:

i. 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).

ii. Do you have a view on the methodology used to estimate the amount of proceedings? If so please give your reason(s).

iii. Do you have a view on the methodology used to estimate the drug driving casualties baseline? If so please give your reason(s)

iv. Do you have a view on the methodology used to estimate the casualty savings? If so please give your reason(s).

v. 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).

Question 8: 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).

Additional evidence on costs and benefits (Q7)

8.3 Altogether nine of the total 43 respondents (all organisations) made a comment at Question 7. Three of these simply stated that they had no additional evidence to offer. Thus, analysis related to this question was based on comments submitted by six respondents.

8.4 Two respondents (both alcohol and drug partnerships) noted that the proposals may result in an increase in cost to community justice services (including the police) at a time when capacity within these services is already stretched. However, both these respondents also believed that improved detection of drug drivers would have wider social benefits, and in the longer term, financial benefits through the reduction in road traffic deaths and casualties.

8.5 Four respondents offered additional evidence, or queried the methodology used in the impact assessment:

- A research organisation highlighted two recently published studies which suggested that 'diverting law enforcement resources from drink driving to drug driving should be done with care to avoid reducing the positive impact on road safety, as drink driving is generally more dangerous'.
- This same organisation suggested that a small prevalence study in the UK would be beneficial to establish a more accurate baseline from which to start an impact assessment in relation to the new law.
- One respondent from the police commented on question 7(i) about the number of proceedings likely to be taken against those on prescribed medication. This respondent noted that established procedures involved testing for alcohol first, and where alcohol was identified, abandoning any possible drug driving offence. It was suggested that the new regulations would result in an increase in detection of drugs where alcohol is **not** present, and that some proportion of these new offences may include people who are on prescribed medications. However, it would be impossible at this stage to estimate the scale of these detections.
- A private sector respondent commented on question 7(ii) about the methodology used to estimate the number of proceedings that may result from enforcement of the new offence. This individual cited data from Germany which indicated that there were 20,000 drug driving prosecutions in the first three years after introducing similar legislation,[8] and after seven years, there were 35,000 drug driving (not drink driving) prosecutions per year. This same respondent commented on question 7(iv) saying that if a similar methodology was used for estimating reductions in casualties as was used for estimating the number of proceedings, the reductions in casualties would be very large, and would result in substantial savings to the NHS. This respondent felt the Government should be less concerned about how accurate the various estimates are, and instead should start the process and 'see just how successful it really is'.
- A respondent from a medical / clinical organisation commented on question 7(iii) about the methodology used to estimate the drug driving casualties baseline. This respondent noted that the estimate of the casualties baseline appeared to take no account of the possible combined use of any of the mentioned drugs – whether alongside alcohol or not. This respondent suggested that, therefore, it was possible these effects had been under-estimated.

Business impact (Q8)

8.6 Altogether, 15 of the 43 respondents (all organisations) made a comment at Question 8. The following is a list of the potential business impacts highlighted by respondents.

[8] It is not clear from this response whether this figure is an annual figure, i.e. 20,000 prosecutions per year in the first three years, or a total figure for three years.

- **Organisations that provide training, awareness raising, road safety advice and materials**: These organisations would include, for example, the AA, Institute of Advanced Motorists, and the Royal Society for the Prevention of Accidents. The point was made that existing information will need to be updated in light of the new regulations.
- **Healthcare professionals**: These included doctors and pharmacists. Community pharmacists were considered to be well placed to deliver information to members of the public about the new legislation. However, many community pharmacists are already stretched in terms of workload and any publicity campaign would therefore need to be paid for by the Government.

  It was suggested that doctors considering prescribing any of the listed medicines in the regulations should give the patient a brief explanation of the new regulations, so that the patient can make an informed decision about whether they wish to take the medication. However, patients (particularly those who are older, or anxious) will not always remember information given to them by their doctor. Therefore, pharmacists will need to repeat the information given by the prescriber. In addition, pharmacists will also have to inform: (i) existing patients on repeat prescriptions (many of whom will not routinely see their prescriber); (ii) those who are prescribed or are purchasing over the counter medicines containing codeine or dihydrocodeine; and (iii) other patients or members of the public who may hear about the new offences, but have not heard or understood the details. These discussions will require careful explanations and are likely to be time consuming.
- **The police**: It was suggested that further detailed comments on the impact of the legislation would be provided from a Police Scotland perspective at the point at which the Scottish Government produces its own Business & Regulatory Impact Assessment. However, the point was also made that the proposed new regulations are likely to require considerable investment in terms of research, development and delivery of new operational procedures, and to have an impact on the workload of operational police officers at a time when capacity is already stretched. In addition, the purchase, provision and maintenance of approved drug screen devices will also have significant financial implications for the police.
- **The Court Service**: It was noted that the proposed changes in legislation are likely to result in an increase in prosecutions. This will have implications for the scheduling of business in the courts. Moreover, if there is a wish to track the number of offences, drugs involved and reading levels, substantial changes would be required to Scottish Court Service (SCS) IT systems and administrative procedures. There will also be a requirement to link data between SCS and DVLA. These changes will have cost implications and will require a few months lead in time.
- **Alcohol and drug treatment / rehabilitation services**: It was thought that these services may see an increase in referrals in line with an increase in detection of drug driving.
- **The DVLA**: It was thought there would be a significant impact on the DVLA – particularly if a High Risk Offenders (HRO) scheme is also implemented. Changes

will be required to IT systems and new medical examinations will need to be introduced. There will also be additional reporting requirements from the DVLA to monitor the impact of the new offences. Further work and discussion is required to agree when and how offences should be recorded. There was also a concern expressed that there may be an increase in (inappropriate) cases sent to the DVLA from the police, as some cases may be difficult to prove in court.

- **Private companies involved in the manufacture and sale of drug screening devices**: These companies are likely to see growth in their sales to police forces. In addition, these companies are often involved in education and training on drugs and alcohol to UK companies, and in workplace drug and alcohol screening. This market is also likely to grow in response to the change in legislation.
- **Businesses in general:** It was suggested that businesses would see a reduction in accidents and incidents involving company vehicles as a result of the new legislation. There may also be an impact on self-employed people who drive for a living (for example, taxi and lorry drivers), and who are also taking analgesics for pain-relief.

8.7 Finally, there was also a view that the proposed legislation would have a **positive** impact on communities, by making communities safer.

9. RESPONDENTS' OTHER COMMENTS

9.1 In addition to their comments on the questions posed in the consultation document, respondents also sometimes made comments that were not directly related to the consultation questions. These addressed a range of topics which are summarised in the points below.

- Respondents occasionally expressed concerns about the implementation of the regulations, and the potential for an adverse impact on people who are legitimately taking prescribed medication for a long-term condition or to treat chronic pain. These comments generally came from charitable organisations that work with people in these situations. It was felt that the proposed legislation would put an 'unfair burden of proof' upon these (in some cases, vulnerable) individuals to demonstrate their innocence when, in fact, no crime had been committed.
- Related to this point, some respondents called for a public health campaign to make members of the public aware of the change in legislation and to ensure that patients are aware of both their rights and responsibilities.
- Some respondents also called for the careful monitoring of the impact of the changes in legislation – to identify any unintended negative impacts on people living with long term conditions and chronic pain. One respondent also thought there should be scope for reviewing the threshold associated with each drug.
- Other respondents emphasised that prescribers have a duty to ensure that their patients understand when their medication may impair their driving skills. While these respondents recognised the importance of supporting people living with chronic pain to maintain independence, they also felt it was reasonable that patients should not drive if there is the possibility of putting other road users at risk.
- While some respondents called for the police to be well equipped, supported and adequately resourced to enforce the new regulations, there was also a view that 'road collisions are caused by a wide variety of factors' and 'resources should be allocated proportionately to the level of risk the various factors present'.
- Respondents frequently called for information ('robust guidelines') to be made more widely available to medical practitioners / prescribers about the implications for patients of driving when taking certain prescribed medications. It was pointed out that medical practitioners do not always advise patients about the effects of certain medications on their fitness to drive, and it was suggested that systems may need to be put into place to support doctors / prescribers with this. One respondent, a medical / clinical organisation, suggested using a similar tool to that used in the Netherlands, where a 'traffic light system' is used on medication packets. Under this system, red means it is unsafe to drive, amber indicates caution should be taken, and green means that the medication will not cause impairment to driving ability. It was suggested that in the absence of good information, there may be under-prescribing of medication to allow patients to continue to drive. This could then result in patients being impaired in their driving as a result of severe pain.
- Respondents also frequently emphasised the importance of 'proper reporting to the DVLA' of medical conditions and medication that can impair driving. It was noted

that current procedures rely on patients to self-report – and that this did not always happen. Respondents suggested that there needed to be a review of how these procedures were working, and that arrangements should be made for doctors (and potentially, other third parties) to more easily report patients to the DVLA when their driving was likely to be impaired by their illness or their medication.

- Related to this, the point was also made that if the DVLA routinely received reports on patients whose medical conditions or medication may affect the safety of their driving, it would be less of an administrative burden to deal with the enforcement of the legislation, since the police would only need to contact the DVLA medical team for information.
- A simple procedure for allowing the police to verify a person's claim to a medical defence needs to be developed. This procedure should not result in taking health professionals away from patient care.
- There were concerns voiced about the potential for breaches of data protection if the police ask a pharmacist for verification of details of an individual's prescription in circumstances where there has been no explicit consent given by the patient to the disclosure. One pharmacy organisation commented that, although the Data Protection Act allows confidential information to be disclosed without consent for the purpose of detecting serious crime, the issue of drug driving was not necessarily seen as a 'serious crime'. There needs to be a system put in place to record patients' consent to disclosure. This could result in a significant administrative burden being put on pharmacists to check for patient consent.

9.2 Finally, there were queries about a statement in the consultation document (paragraph 17.1) that 'the police have powers to require individuals arrested or charged with an offence (who test positive for heroin or cocaine / crack) to attend up to two assessments with a qualified drug worker'. One Scottish respondent (an alcohol and drug partnership) commented that the medical practitioners in their area pointed out that it is the courts and procurators fiscal – not the police – who have the power to mandate drug treatments in Scotland. This respondent wanted clarification about whether the proposed changes in legislation would include changes to this existing arrangement, as there could be significant implications for drug services if the police were given powers to mandate treatment for individuals arrested for drug driving. At the same time, other respondents did appear to be in favour of linking arrests for drunk driving to a referral to treatment / recovery services.

ANNEX 1: ORGANISATIONAL RESPONDENTS

Alcohol and drug partnerships (5)

- Angus & Perth & Kinross Alcohol and Drug Partnerships
- Borders Alcohol and Drug Partnership
- Lanarkshire Alcohol and Drug Partnership
- Renfrewshire Alcohol & Drug Partnership
- West Dunbartonshire Alcohol and Drug Partnership

Other public sector organisations (4)

- Police Scotland (Road Policing)
- Scottish Court Service
- Scottish Fire and Rescue Service
- South Lanarkshire Council

Medical, clinical and research bodies (7)

- British Medical Association (BMA)
- European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- Faculty of Pain Medicine, Royal College of Anaesthetists
- Independent Scientific Committee on Drugs
- NHS Grampian, Public Health Directorate
- Royal College of Physicians and Surgeons of Glasgow
- The Royal College of Surgeons of Edinburgh

Pharmacist groups and pharmaceutical bodies (6)

- Accountable Officer Network Scotland Group
- Pharmacy Substance Misuse Advisory Group and College of Mental Health Pharmacists
- Pharmacy Voice Limited and Pharmaceutical Services Negotiating Committee
- Royal Pharmaceutical Society (RPS)
- Scottish Palliative Care Pharmacist Association (SPCPA)
- United Kingdom Clinical Pharmacy Association

Road safety, motoring and licensing organisations (8)

- Automobile Association (AA)
- Brake
- DVLA
- Institute of Advanced Motorists (IAM)
- Living Streets
- Royal Society for the Prevention of Accidents
- Shetland Road Safety Advisory Panel
- Supporting Victims of Road Crashes (SCID)

Charitable organisations and forums supporting patients with chronic pain (5)

- Chronic Pain Policy Coalition (CPPC)
- National Rheumatoid Arthritis Society (NRAS)
- Pain Concern
- Pain UK
- The British Pain Society

Private sector organisations (3)

- Association of British Insurers
- D. Tec International Limited
- Draeger Safety UL Ltd

Other organisational respondents

- Fast Forward

ANNEX 2: NUMBER OF RESPONSES RECEIVED, BY QUESTION

Question		Number of organisational responses	Number of individual responses	Total number of responses
Q1	Do you agree with the Government's proposed approach as set out in policy option 1? If not please provide your reason(s).	39	4	43
Q2	Do you have any views on the alternative approaches as set out in policy option 2 and 3?	30	3	33
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?	23	1	24
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?	29	3	32
Q5	Do you have a view as to what limit to set for amphetamine? If so please give your reason(s).	19	1	20
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).	22	0	22
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 at Annex D? For example: i. 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). ii. Do you have a view on the methodology used to estimate the amount of proceedings? If so please give your reason(s). iii. Do you have a view on the methodology used to estimate the drug driving casualties baseline? If so please give your reason(s) iv. Do you have a view on the methodology used to estimate the casualty savings? If so please give your reason(s). v. 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).	9	0	9

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).	15	0	15

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