NEW ZEALAND POLICE
Ngā Pirihimana o Aotearoa

Memorandum

To: Oral Fluid Testing Governance Board (OFTGB)
Prepared by: Oral Fluid Testing Project
Date: 15 September 2022
Subject: OFT Device Procurement Update

Purpose

1. s9(2)(h) [redacted]
This memorandum provides the board with an update on those challenges, taking into account the availability of more recent information and outlining the options as identified by the project for consideration and discussion by the board.

Executive Summary

2. s9(2)(h) [redacted] validating the accuracy of the device to enable both public and other stakeholders to build trust and confidence in both the device and process.

3. As part of the due-diligence, independent device verification testing results have shown the three devices short-listed have not met the levels requires as set out in the relevant Standard.

4. The failure to meet the require verification levels confirms the previously held and shared view that the current technology of OFT devices doesn't align with the amendments as introduced through the Land Transport (Drug Driving) Amendment Act 2022 (The Act).

5. A number of steps have been introduced to identifying alternative devices (to meet the requirements of the Act) and determining why the initial shortlisted devices failed to meet the verification as set out in the Standard.

6. The impact of the outcomes of these due-diligence activities will likely impact the ability of New Zealand Police (NZP) to conduct roadside testing according to the timelines as set out in the Act.

7. The impact of the device technology only allowing for the testing of THC (the psycho-active ingredient in cannabis) and cocaine which falls short of detection of the most prevalent drugs has the ability to undermine the intent of the Act in reducing the number of deaths on the road whilst also impacting on the level of trust and confidence in NZP.

Recommendations

It is recommended that the Board:

a)	**Note** the contents of this memorandum.	Noted

[1] s9(2)(h) [redacted]

b)	**Note** based on current understanding that current device technology doesn't allow for operationalisation of a random roadside drug test as the amended Act intended.	Noted
c)	**Note** based on current understanding that the limitation of which drugs can be effectively tested for at the roadside using available technology, is limited to THC and cocaine.	Noted
d)	**Note** that though the technology is capable of testing for THC, there are difficulties when presented with a positive result for presence of THC due to prescription medication and in relation to 'recent use'.	Noted
e)	**Note** that the project will develop a detail options analysis of the identified options for presentation to the Board.	Noted

Introduction

8. Several legal and illegal drugs impair driving ability and increase the risk of crashes. New Zealand drivers are driving under the influence of these drugs which is causing significant harm. In 2020, 115 people were killed and 214 people were seriously injured in crashes where illegal drugs were a factor[2].

9. In 2019, following public consultation on several policy options, the Government elected to introduce compulsory random roadside oral fluid testing (OFT) with the aim of reducing road trauma and making our roads safer [DEV-19-MIN-0360 refers]. Delivery of OFT is a key action under Road to Zero, the Government's road safety strategy for 2020 to 2030. The strategy sets a target of a 40 percent reduction in deaths and serious injuries on our roads by 2030.The Land Transport (Drug Driving) Amendment Act 2022 (the Act) comes into effect in March 2023 following its successful completion of the Parliamentary process on the 11 March 2022.

10. Among the implications of the Act, it includes ability for New Zealand Police the stop any driver of a motor vehicle and administer an OFT at the roadside without the need to have good cause to suspect a driver has consumed drugs (random testing).

11. To administer the roadside OFT, a device is required which must be approved by the Minister of Police. When approving any device, the Minister of Police is required to have consideration of the following:

    - consult with the Minister of Transport and Research, Science and Innovation Minister
    - consider the accuracy of the device
    - be satisfied that the device will only return a positive result if it detects the presence of a qualifying drug at a level that indicates recent use
    - take into consideration any relevant New Zealand or joint Australian and New Zealand Standards for the device[3].

12. Once a device is approved by the Minister of Police, as part of the Gazette Notice publication, the Notice must be published specifying the approved device and the in-built concentration level for each qualifying drug that indicates recent use of a specified qualifying drug.

13. To provide evidence to the Minister of Police as part of the submission for approval, within the device due diligence, the short-listed devices were to be sent, under the management of an independent expert in the field, to a laboratory for independent testing and verification on accuracy.

14. To determine accuracy, the laboratory to test was based upon the criteria as set out in "Appendix C: Verification of performance of devices used for the collection, on-site testing, transport and storage of oral fluid specimens" of the Standard.

15. Appendix C: Verification of performance of devices used for the collection, on-site testing, transport and storage of oral fluid specimens required that 20 devices are tested, 10 with a spiked oral fluid sample with concentration levels of the drug at -50% or the cut off level and 10 samples with a spiked oral fluid sample with concentration levels of the drug at +50% or the cut off level. To test allows for a failure rate of 10%, i.e., no more than two failures in total.

16. Upon verification of the device to the criteria set out in the standard, it would be proposed on an evidential basis that the device has consideration for accuracy, **with** the probability of returning only positive results if it detects

[2] Based on data for all crashes reported by Police to Waka Kotahi for 2020 as recorded in the Crash Analysis System as of 19 July 2021

[3] AS/NZS 4760:2019 Australian/New Zealand Standard - Procedure for Specimen Collection and the Detection and Quantification of Drugs in Oral Fluid

the presence of a qualifying drug at a level that indicates recent use and had consideration of the Standard relating to OFT device.

17. Having completed the laboratory test of the shortlisted devices, all of these have failed to meet the criteria as set out within the Standard.

18. When considering the operational functionality of a device at the roadside, for the purpose of issuing an infringement based on the positive result of the testing procedure, it can be considered that to fairly inform the driver of a positive result, the device must be able to identify the specific drug for which the driver has returned the positive result.

19. Due to the likely significant public interest in the efficacy and effectiveness of the new OFT device before and after implementation (similar to what has historically been as seen with the roadside alcohol breath test), s9(2)(h) [redacted]

Historical background

When reviewing this Memorandum, the following information data points are provided which provide context to the challenges which are prevalent within the procurement process.

20. In December 2019[4], it was noted by Cabinet that based upon crash risk of drugs and the prevalence of their of use by New Zealand drivers, the drugs or drug classes that will be tested for as part of the oral fluid testing process were to be THC (the psycho-active ingredient in cannabis), methamphetamine, benzodiazepines (sedatives), MDMA (ecstasy), opiates (e.g. morphine), and cocaine.

21. During the drafting process of the amendment, an Independent Expert Panel (IEP) was established to provide independent advice on:

    - 'blood-drug' limits to be specified in legislation (criminal limits)
    - low-level tolerance thresholds to be applied to the detection of drugs in blood (blood infringement thresholds)
    - cut-off thresholds in oral fluid testing devices (oral fluid infringement thresholds).

22. Following the completion of the report[5] by the IEP, where the IEP included advice on oral fluid infringement thresholds and testing devices, a joint brief[6] was provided by both the Ministry of Transport and New Zealand Police which identified:

    - The cut-off thresholds for detection in commercially available testing devices are generally aligned to oral fluid drug concentrations set in Standards. These Standards are most commonly applied to workplace safety but they are relevant for roadside testing. The recommended cut-off thresholds are generally accepted as indicative of recent drug use, rather than historical use or accidental exposure.
    - There is a very poor correlation between blood and oral fluid concentrations. The panel stated that based upon the available evidence, the Panel could not provide oral fluid infringement threshold recommendations that align with the blood infringement threshold recommendations
    - Commercially available oral fluid testing devices lack specificity which may lead to false negative or false positive test results

[4] DEV-19-MIN-0360
[5] Final Report of the Independent Expert Panel on Drug Driving (April 2021)
[6] 20210429 - OC210284 - BR-21-48 - Release of the Panel's final report - Briefing - FINAL

- Oral fluid testing devices can test for sedatives and opiates as a drug class, but cannot identify specific drugs within the class
- The Panel does not recommend procuring a bespoke oral fluid testing device
- The Panel recommends laboratory confirmation of blood concentrations following a positive oral fluid screen

23. The expert panel state when reviewing devices and the relevance of the concentration levels, NZP would undertake confirmatory analyses of blood samples (to verify the accuracy of the roadside test). The assumption that NZP will undertake a confirmatory blood test is invalid as the final legislation does not require a confirmatory testing of a blood sample in a laboratory environment.

Device Technology

24. While advances in this field of technology continues to be made, NZP need to be aware that the current device technology on the market is being pushed beyond the reasonable limit based on how we are intending to use the devices (to meet the current legislation).

25. There is no current roadside OFT devices on the market that can provide the level of accuracy required for an evidential purpose. A number of manufacturers specifically refer to their device as a screening tool with confirmatory analysis required.

> "*The Drug Test provides only a preliminary screening result (initial testing). In case of presumptive positive results, a more specific alternative methodology must be used in a laboratory in order to obtain a confirmed analytical result (confirmatory testing).*"[7]

26. From the market research undertaken as part of the procurement process and following discussion with experts in the field both within New Zealand and internationally, it has been determined that the current marketplace of devices use the same underlining core technology. For the purpose of understanding, this is the same technology that we have seen more recently in devices used for the detection of COVID-19.

27. The IEP state that *it is very important to understand that few of the channels on these devices react to a single drug. This is known as cross reactivity because, due to similarities between the chemical structures of the drugs, the device cannot distinguish between them. The degree of crossreactivity, or the sensitivity of a particular device to drugs not being specifically targeted depends on the specific technology used. This can differ for the different devices available*.

28. From the evidence and through validation in discussion with the experts, of the drugs that were identified as most prevalent to New Zealand Driver, these were only THC (detected in less than 34% of the recent blood samples analysed) and Cocaine (detected in less than 1% of the recent blood samples analysed), were considered viable drugs for testing.

29. Based on the technology of devices and the need to specify the qualifying drug at the point the device detects a positive reading along with when providing the detail required in the Gazette Notice, this excluded:
    - Methamphetamine due to its crossreactivity with MDMA
    - Amphetamine due to its crossreactivity with MDA

[7] Extract from one of the manufacturers brochures provided during the tender process

- Opiates due to being a class of drug rather than a specific qualifying drug. Most devices use 6MAM a metabolite of Morphine as the qualifying drug which the opiate channel detects. 6MAM has a crossreactivity with a number of qualifying drugs that includes heroin, codeine amongst them.

- Benzodiazepines due to being a class of drug rather than a specific qualifying drug. As noted in the IEP report the devices *lack specificity and will detect more than one drug in this class*.

30. As we have seen with COVID-19 tests, these types of devices have limitations are not always accurate. To quote the IEP further directly:

    They do not prove the use of a drug. False positives and false negatives are possible.

    *In the drug driving context, a **false positive** is when a drug is detected by the oral fluid device but is not detected by confirmatory analysis. The inability to confirm a finding may be because, although the drug is present, the concentration is not above the legislative limit. A false positive may also arise from cross-reactivity, where a different drug causes the positive reaction.*

    *A **false negative** result occurs when there is no reaction to the presence of a drug by the oral fluid device, even though the drug is present. Such occurrences are more difficult to determine by confirmatory analyses because, of course, a confirmatory analysis would not usually be carried out on a negative screen test. Some devices are known to give false negative results for high THC concentrations.*

31. The verification procedure of a device allows for a 10 % error rate, though this is based on a 50% variance both positive and negative. With undertaking 66,000 test per year, this equates to 53 instances using the two-test process where the result is either an incorrect false positive or false negative outcome, which could lead to the incorrect issuance of infringement notices.

Cannabis

32. Though THC is detectable within the single channel it is noted that THC is a difficult drug to accurately detect using an OFT device. Oral fluid testing devices are more sensitive to THC-acid than to THC; this might result in false positive oral fluid screen results for heavy cannabis users.

33. Testing for THC at a level which indicates "recent use" is difficult due to the unique characteristics of the drug, with a regular user able to test positive many days after last using the drug.

34. Medicinal cannabis is now available by prescription and as of August 2022 there were 18 products available on the market. Since March 2022, seven dried cannabis flower products with a level of 1-25% THC have been introduced to the market. The THC levels in the cannabis mean the quality of the product is just as good, if not better, than what people can purchase from their local dealers[8].

35. There is already an increasing trend of people attempting to access cannabis through legal prescriptions, with very loose guidelines currently in place for processes regarding gaining access to the products.

36. A number of the products are leaf material, and while it is subject to the requirements under the Medicines Act 1981 (to be carried in a labelled container), s9(2)(g) [redacted]

37. s9(2)(g) [redacted]

[8] Introduction of Medicinal Dried Cannabis Flower Products - National Drug Intelligence Bureau INTELLIGENCE NOTIFICATION

Outcome of Independent Device verification

38. The three shortlisted devices as recommended by the Tender Evaluation Team (TET) were sent for an expert independent review which included being independently lab tested. All three of the devices failed on the THC verification, with one also failing methylamphetamine (meth) standard, and another on the amphetamine verification. The failures were due to the high amount of 'false positive' and 'false negative' results falling outside the acceptable range.

39. One of the devices also failed with regards to detecting THC where it returned two positive results from blank samples. Of note (and by coincidence only) the lab conducting the independent testing on the behalf of NZP was the same lab which had completed the independent testing report provided by one of the manufacturers.

40. Subsequently, enquiries are being made to clarify the disparity between the results seen by NZP and that provided by the vendors proposing the devices. Information obtained could potentially explain the results disparity, with a specific point of note relating to the type of saliva used for sample testing. NZP had testing carried out on authentic saliva samples as this replicates the most authentic real-world scenario.

41. s.9(2)(g) OIA [redacted]

Summary of challenges

42. Availability of a device to meet the legislation due to the current foundation technology.

43. Due to the device technology constraints, the need to publicly state the qualifying drug and its concentration level along with the need to fairly inform the driver of the qualify drug for which they test positive, operational testing of drugs is limited.

44. Within the crash data, the two most prevalent drugs are cannabis and methamphetamine. With both of these drugs being difficult or impossible to establish specific consumption, this limits the opportunity for the OFT to deliver upon is objective of being an effective deterrent for drivers having recently consumed impairing drugs.

45. The current legislation makes it extremely difficult to test for prescription drugs at the roadside using existing technology, as it cannot distinguish between the individual qualifying drugs within those family of drugs.

46. With no requirement to undertake a confirmatory analysis in some form (as is practice in all other jurisdictions who undertake OFTs, the use of today's technology doesn't meet the requirements of the Act as amended in attempting to use the available technology as is, it limits the ability of NZP to deliver against the intent of the Drug Driving legislation. s9(2)(g) [redacted]

Next Steps - Options available

47. The TET met and have agreed to submit the remaining five (potentially suitable) devices for independent verification test.

48. The manufacturers of the previously tested three devices that did not meet the verification standard have been contacted to provide insight into why the results differed from those provided as part of the procurement process.

49. Re-scan of the market to identify any new devices.

50. In addition to the above steps, a number of scenario based options have been identified that cover the outcome of whether or not a device suitable device is identified, the draft details of which are set out in Appendix 1, which the project are developing (noting no analysis is provide for option 5):

1	If a suitable device is identified (through the validation of independent testing to the Standard), then proceed with the current technology and Act on the basis a device will be procured to test at the roadside only for cocaine and THC.
2	NZP to look at implementing a process by which all positive OFT results are sent a lab for confirmatory testing of the oral saliva. This will require an amendment to the Act as currently there is no provision for this. This includes the seizure and analysis of oral fluid samples beyond the roadside.
3	NZP do not commence OFT on 11 March 2023 but implement the other amendments resulting from the Act i.e. infringement notices and blood testing (resulting from Compulsory Impairment Testing and/or vehicle crashes). Once a technology is available that delivers the operational capability NZP would then implement OFT roadside testing.
4	Amend the Act to align with current device technology (as is practised in overseas jurisdictions).
5	If no device meets the verification standard, continue as is and implement a device based on current technology and Act on the basis a device will be procured which test at the roadside for cocaine and THC. This potentially carries significant community and organisational risk.

Appendix 1 – Draft Options Analysis

Option 1: A device is procured which meets the validation criteria as set out in the Australia New Zealand Standards (Appendix C)	
Overview:	One of the current devices being independently tested meets the required standards set by AS/NZS 4760:2019.
Drugs tested for at the roadside:	• THC • Cocaine
Dependencies:	• Requires a device to be gazetted which meets the required standards
Positives:	• Requires no amendments to the current legislation • Most viable option for delivering restricted OFT in March 2023 • Device available which tests for qualifying drugs • Testing in some capacity can assist general deterrence for drug driving • Does not require any legislative changes to proceed • Immediate issuing of an infringement notice being an important aspect of achieving deterrence
Negatives:	• No confirmatory testing to be undertaken to confirm the result • Restricted by current legislation and current available technology to only test for two drugs at the roadside • THC has the highest detection rate in blood testing however presents difficulties for detecting 'recent use', and is further complicated by introduction of medicinal cannabis – impact on PIB medical defence referrals • While there could be a reasonable level of confidence in testing for cocaine, there is a current less than 1% detection rate on our roads for cocaine • The device is going to be open to legal challenges regarding the accuracy

Option 2: A device is procured which meets the validation criteria as set out in the Australia New Zealand Standards (Appendix C) and a confirmatory test is completed on all OFT positive results	
Overview:	One of the current devices being independently tested meets the required standards set by AS/NZS 4760:2019. In order to build confidence in the programme NZP undertake a confirmatory test on all positive OFT results prior to any enforcement action being taken. This would involve the second sample being used to confirm the result and then being sent to a laboratory for a confirmatory test.
Drugs tested for at the roadside:	• THC • Cocaine
Dependencies:	• Requires a device to be gazetted which meets the required standards • Almost certainly requires a legislative amendment to the Act • Understanding of drafting considerations of legislation
Positives:	• Most viable opportunity for mitigating organisational risk and delivering OFT in March 2023 • Device available which tests for qualifying drugs • Testing in some capacity can assist general deterrence for drug driving • The addition of a confirmatory analysis (while not required) will provide for a level of trust and confidence in the OFT process and device • Removes most avenues for challenging the accuracy of the device • Removes the impact for false positive results

	• There is potential for a confirmatory analysis to reduce the number for blood tests being sought, with a potential cost saving • Removes the financial constraints on the driver to challenge the outcome of an OFT
Negatives:	• Restricted by current legislation and current available technology to only test for two drugs at the roadside • Currently the ingredients to prove an OFT offence requires two positive OFT results for the same qualifying drug using an OFT device, meaning there is no lawful requirement in proving an offence by undertaking a confirmatory test • THC has the highest detection rate in blood testing however presents difficulties for detecting 'recent use', and is further complicated by access now to medicinal cannabis • While there could be a reasonable level of confidence in testing for cocaine, there is a current less than 1% detection rate on our roads for cocaine • Currently there is nothing written into the Act that allows police to lawfully use a driver's oral fluid sample for enforcement purposes for anything beyond the roadside test. It is likely that a legislative change would be required to facilitate this occurring • delays in enforcement action pending the result of the confirmatory test • Requires a chain of custody process to be implemented for facilitating the oral fluid sample reaching the laboratory

Option 3: No device – wait for available technology to align with the legislation	
Overview:	None of the tendered devices meet the requirements to be approved by the Minister. Random roadside testing is not delivered for March 2023.
Drugs tested for at the roadside:	• Nil
Dependencies:	• Future technology becoming available in the market

Positives:	• Remaining legislation can still be delivered
	  • New blood sample analysis processes
	  • New offences
	• Potentially maintain public trust and confidence by ensuring any new legislation enacted is effectively operationalised and aligned to the intent of The Act
	• No impact to current staff deployment or roadside testing processes

Negatives:	• Unknown timeframes for when technology advances will be available • There is agreed funding to deliver 33,000 tests in the first 12 months of deployment • Political implications of not being able to operationalise the OFT aspects of the legislation • No ability to impact on general deterrence of drug driving with no changes to current impaired driving processes

Option 4: Legislative changes to the Act relating to OFT	
Overview:	Potential changes to the Act could include: 1. Removal of the requirement for '*two positive results for* ***the same qualifying drug'***. 2. An additional amendment for a confirmatory test to be conducted following two positive OFT results for a qualifying drug. 3. An amendment to provide the lawful authority to use an oral fluid sample for the purpose of conducting a confirmatory test.
Drugs tested for at the roadside:	• THC • Cocaine • Methamphetamine • MDMA • Potential to look at prescription drugs
Dependencies:	• Ability to make amendments to the legislation
Positives:	• Could open the door for the families of drugs to be tested for • Provide confidence in the OFT testing programme • Usage of any device will comply with manufacturers recommendations • Increased general deterrence factor through increasing the number of drugs tested for at the roadside to include all of the most prevalent drugs currently being detected • Reduces the accuracy requirements on any selected OFT device • Confirmatory test can remove the ability to challenge the accuracy of any selected device • Potential cost savings on completing confirmatory saliva testing as opposed to driver's electing blood samples
Negatives:	• Requires changes to the current legislation • A confirmatory test would be a requirement if the wording was changed to allow detection of families of drugs (based on current available technology) • Would require delaying the implementation of the new legislation • Additional costs and training for chain of custody with oral fluid samples being sent for lab analysis (there is an ability to utilise current refrigerator resources available to CVST and IPT) • Confirmatory tests can lead to delays in enforcement action being taken