Psychoactive Substances Act 2016

Forensic Strategy

The Psychoactive Substances Act 2016 (the PS Act) differs from the established approach to drug control under the Misuse of Drugs Act 1971 (MDA). The PS Act covers substances by virtue of their psychoactive properties, rather than the identity of the drug or its chemical structure. Consequently, there is a requirement for a new forensic capability.

This strategy sets out guidance for Forensic Service Providers (FSPs), law enforcement agencies, prosecuting agencies and expert witnesses to support the operation of the PS Act. It provides guidance on the scientific principles for the new testing regime and the process and evidential considerations to support criminal and civil sanctions under the PS Act. The strategy has been developed by the Home Office with input from the Advisory Council on the Misuse of Drugs (ACMD).

This strategy does not relate to those drugs controlled under the MDA which remains the primary legislation for drug control in the UK. For controlled drugs, the normal forensic and evidential processes and requirements apply.

Background

The PS Act and explanatory notes can be found at: www.legislation.gov.uk/ukpga/2016/2/contents/enacted/data.htm. It comes into force on 26 May 2016.

It creates a number of criminal offences covering the manufacture and distribution of a psychoactive substance (as defined in the PS Act). The PS Act creates offences related to the production, supply or offer to supply, possession with intent to supply and importation or exportation of a psychoactive substance for human consumption. There is no possession offence except in the context of possession inside a custodial institution. In addition to the criminal offences, the PS Act also creates four civil sanctions, namely prohibition notices, premises notices, prohibition orders and premises orders. These provide an alternative to criminal proceedings and a means to use a graded approach to enforcement action.

The PS Act captures all psychoactive substances that are **not** controlled by the MDA or are otherwise exempt[1].

[1] The list of exemptions covers medicinal products as defined by the Human Medicines Regulations 2010, alcohol, nicotine and tobacco, caffeine and food. In addition, Schedule 2 of the Act lists certain exempted activities.

Definitions in the PS Act

A psychoactive substance is any substance which is: *'capable of producing a psychoactive effect in a person who consumes it'* . . The PS Act only captures substances which are distributed for human consumption for their psychoactive effects[2].

For the purposes of the PS Act, a substance produces a psychoactive effect if, '*by stimulating or depressing the person's central nervous system, it affects the person's mental functioning or emotional state*.'

The Explanatory Notes to the PS Act elaborate on this with the following description: '*by speeding up or slowing down activity on the central nervous system, psychoactive substances cause an alteration in the individual's state of consciousness by producing a range of effects including, but not limited to: hallucinations; changes in alertness, perception of time and space, mood or empathy with others; and drowsiness*.'

Demonstrating "psychoactivity" for the purposes of the PS Act

In line with guidance provided by the ACMD, where *in-vitro* testing is available it should be used to demonstrate a substance is *'capable of producing a psychoactive effect in a person who consumes it'* (psychoactivity) for the purpose of the PS Act (see next section).

In-vitro tests are not suited to all types of substance. Most notably, nitrous oxide and solvents cannot easily be subjected to *in-vitro* testing. In these cases, alternative sources of evidence will need to be used including published literature. There is a wealth of evidence available on both *in-vitro* and *in-vivo* studies carried out by academic researchers which can be referenced by expert witnesses[3].

Whether in addition to, or in the absence of, *in-vitro* tests it remains open for expert witnesses to draw on and adduce any other relevant evidence, including published literature, other research and studies into the substance, where they are admissible[4]. Other evidence, for example, accounts from a witness of behaviour exhibited by an individual who has taken the substance, may also be relevant.

Guidance from the Advisory Council on the Misuse of Drugs

To support the operation of the PS Act, the ACMD provided the following guidance[5], based on the known basic pharmacological activities of existing psychoactive substances:

[2] All other circumstances in which these substances are produced and distributed, including the transmission of chemical reference standards and seizures for forensic testing, are outside of scope of the PS Act.
[3] The Home Office has commissioned a review of literature on nitrous oxides and solvents to support cases on these specific substances.
[4] The admissibility of evidence is ultimately for the court to determine.
[5] www.gov.uk/government/uploads/system/uploads/attachment_data/file/470421/ACMD_definitions_advice_final-23-October-2015.pdf

> ‘A substance produces a psychoactive effect in a person if, by stimulating or depressing the person’s central nervous system, it affects the person’s mental functioning or emotional state; as measured by the production of a pharmacological response on the central nervous system or which produces a response in *in-vitro* tests qualitatively identical[6] to substances controlled under the Misuse of Drugs Act 1971, and references to a substance’s psychoactive effects are to be read accordingly.’

The ACMD identified examples of classes of substances that come under the provisions of the PS Act, to include, but not limited to: all stimulants, dissociatives, hallucinogens, substances acting through the endocannabinoid system, the opioid system and the GABAergic system[7], which are not already covered by MDA.

The fundamental science of the *in-vitro* test

In-vitro testing can be defined as tests that take place outside the body e.g. in a test tube or on a glass plate.

A receptor is a structure or molecule which is situated on a cell membrane (or inside the cell). When a drug binds to a receptor it can activate it and this activation leads to a response – the physiological effects associated with the drug. For example, when cannabis is taken, the active ingredient (THC) makes its way through the body and binds to the CB_1 receptor. The THC activates the receptor, which then goes on (via a network of signals and processes in the body) to produce the effects on the body that are associated with cannabis (relaxation, time distortion etc.). Receptors are not activated by just one drug – groups of drugs which have a similar 3D shape will bind to and activate the same receptor. Synthetic cannabinoids are a group of drugs taken because they produce similar effects to cannabis. These drugs would be expected to bind to the CB_1 receptor and activate it.

The ACMD has recommended two tests:

> (1) receptor binding assay (to determine whether the drug binds to the receptor); and
>
> (2) a functional assay (to determine whether the drug activates a response following interaction with the receptor).

In both cases testing is done in the laboratory by immobilising cells that have specific receptors, exposing them to a drug and measuring the response.

The receptors which have been selected for testing are:

- CB_1 (targeted by cannabis and synthetic cannabinoid type drugs);

[6] “qualitatively identical to” means that the substance interacts with the same target as a known psychoactive drug controlled under the Misuse of Drugs Act 1971.

[7] These systems describe the way that drugs interact with the body and the body’s response. Drugs target specific parts of these systems and when they interact with them, the body responds by producing the effects associated with families of drugs.

- $GABA_A$ (targeted by benzodiazepine type drugs);
- $5HT2_A$ (targeted by hallucinogenic type drugs – these can be from a number of different types of drugs);
- NMDA (targeted by dissociative/hallucinogenic drugs e.g. ketamine);
- μ-opioid (targeted by opioid drugs e.g. heroin); and
- monoamine transporters (targeted by stimulant drugs e.g. MDMA, cocaine).

The receptor and functional assays have been selected to cover a range of psychoactive substances that have been encountered in Europe. Additional receptors may be added in the future if different drugs or mechanisms of drug action appear. This will be kept under review by the Home Office in consultation with the ACMD.

Home Office programme of *in-vitro testing*

To support the operation of the PS Act in its initial stages and pursuant to the guidance from the ACMD, the Home Office has put in place a programme of *in-vitro* testing.

The Home Office's Centre for Applied Science and Technology (CAST) has developed a technical specification for the testing[8]. A commercial supplier has been contracted to perform the testing for a range of Certified Drug Reference Standards (CDRS) of substances detected in the UK in the last year.

CDRSs are pure samples of a drug which are already used to identity a drug or its chemical structure in law enforcement seizures. These (rather than case samples) will now be tested in the *in-vitro* testing. If the CDRS is shown to be psychoactive, the FSP will only need to identify the substance chemically and the results from the *in-vitro* testing can be applied for each case. The FSP can then report the results to the law enforcement agency within normal timeframes.

The *in-vitro* test will produce the necessary data, set out in a report, to indicate that a substance is *capable* of producing a psychoactive effect in a person. For most of the assays it would require both the binding and functional assays to be positive for the substance to be considered psychoactive. There will be further information available from the tests to provide additional detail on the extent and type of binding if considered necessary.

The technical specification for the *in-vitro* testing, which outlines both the technical and quality standards which provides the assurance of evidential quality, has been endorsed by the Forensic Science Regulator. The Forensic Science Regulator statement is attached at Annex A.

The test will not provide information on the potency of a specific compound. When an expert witness interprets the data they might make hypothetical comparisons to controlled drugs, but direct comparison on potency will not be possible or necessary.

[8] Specification for In-Vitro Testing Substances (version 2.0, dated 20 April 2016)

Initially, the test results will be held by CAST who will maintain a central reference bank of the data. These data will be made available to FSPs, law enforcement agencies and expert witnesses at no cost. During this time, as deemed necessary, CAST will arrange for CDRS of substances to be purchased and tested both proactively (led by intelligence including collection plans under the Home Office Forensic Early Warning System III) and reactively (where law enforcement encounter substances for the first time).

Processing a seizure of suspected psychoactive substances

Annex B provides additional guidance on the enforcement and evidential process.

Law enforcement agencies and FSPs should confirm local processes for submission, retention and storage following initial seizure of a suspected psychoactive substance.

With the exception of custodial institutions, there is no possession offence under the PS Act. However, any enforcement officer[9] who is exercising the power to **search** under the PS Act may seize and detain anything found in the course of the search and which the officer **reasonably believes** to be, inter alia, a psychoactive substance within the definition of the PS Act. The officer may dispose of the item in whatever way they deem suitable. Forensic analysis is not a requirement in these cases. However, it is likely to be valuable for intelligence purposes as a way of understanding what substances are circulating locally as well as contributing to the national picture.

Due to the dynamic and ever-changing range of substances and their ingredients, forensic analysis should be sought in connection to any consideration of any other disposal (whether a criminal charge or civil action) where the investigating officer reasonably believes that a prohibited activity under the PS Act is being carried out or is likely to be carried out.[10]

Identification

In the event that a FSP has identified a substance in a seized sample which is not a controlled drug under the MDA, they should consult with CAST to check if a CDRS of that substance has previously been subject to an *in-vitro* test as necessary.

Evidential samples are often mixtures of psychoactive substances. When a sample contains such a mixture, controlled substances should be pursued as a priority and consideration given to a prosecution under the MDA. Law enforcement agencies, in consultation with FSPs as appropriate, should take a decision locally whether additional actions under the PS Act should be pursued.

Where the in-vitro test has previously been conducted

[9] Enforcement includes police, UKBF and Trading Standards.
[10] Field testing device for these substances are not available.

As necessary, CAST will supply the enforcement agency and/or the FSP with the report from any *in-vitro* testing and, if available, expert witness statements, or other information. CAST will refer to statements from previous law enforcement activity, including prosecutions where applicable.

Where the in-vitro test has not previously been conducted

Before initiating *in-vitro testing*, the FSP and the law enforcement agency should be satisfied that the substance is not likely to fall under one of the substance exemptions or activity exceptions in the PS Act.

When a FSP confirms with CAST that the identified substance has not previously been subject to *in-vitro* testing and is not exempt, in consultation with the FSP and the law enforcement agency, CAST will decide whether a CDRS of the substance should be purchased and submitted for *in-vitro* testing.

In the event of a new CDRS being *in-vitro* tested, it is paramount that the FSP makes the police aware of this to allow them to consider the effect on bail periods and to progress the case appropriately to optimise turnarounds.

Timescales

FSPs should agree locally with law enforcement agencies the timescales around the testing scenarios described above together with the preparation of expert witness statements.

Evidential considerations

Evidential standards of proof

Prohibition and premises notices (under sections 13 and 14) are granted by a senior officer or a local authority if, inter alia, they **reasonably believe** that the seized substance is a psychoactive substance as defined by the PS Act. Law enforcement agencies and FSPs should confirm processes and forensic evidential packages meet this standard, taking into account all other relevant evidence.

For prohibition and premises orders (under sections 17 and 20), the Court must be satisfied, on the **balance of probabilities,** that the seized substance is a psychoactive substance as defined by the PS Act. Applications to the Court for prohibition or premises orders should be prepared to meet this civil standard of proof. Law enforcement agencies and FSPs should confirm processes and forensic evidential packages meet this standard, taking into account all other relevant evidence.

For prosecutions for offences under sections 4 – 8 or 26 of the PS Act**,** prosecuting authorities will need to establish **beyond reasonable doubt** that, inter alia, the seized substance ‘is *capable* of producing a psychoactive effect in a person who consumes it‘. All cases that are being considered for criminal prosecution will require a full forensic evidence pack to support this course of action.

Forensic Evidence Pack

Considerations in different jurisdictions in the UK

Expert evidence and the material underlying it must be admissible in criminal proceedings in all three jurisdictions, England & Wales, Northern Ireland and Scotland as appropriate. Evidence must be given by witnesses qualified to establish to the satisfaction of the court the seized sample contains a substance that is not a controlled drug or a substance otherwise exempt under the PS Act, and that the substance is *capable* of having a psychoactive effect within the meaning of the PS Act.

For England and Wales, the underlying statements must comply with s. 9 Criminal Justice Act 1967 (CJA 1967). For Northern Ireland, they must comply with s. 1 of the Criminal Justice (Miscellaneous Provisions) Act (Northern Ireland) 1968.

For Scotland, corroborated evidence is required from those who carry out the *in-vitro* testing and also from the expert witnesses who interpret those results and speak to the capacity of a substance to produce a psychoactive effect as defined in the PS Act. The Criminal Justice Act 1967 does not apply in Scotland. Technical or expert evidence should therefore be provided in the form of a joint report.

The statement of the Forensic Science Regulator referred to above applies across the UK.

Statements

A *full* forensic evidence pack provided via the FSPs should contain the following:

- Statement from the FSP, compliant in the relevant jurisdiction, confirming the identity and quantity of the substance and confirming that it is not a controlled drug under the MDA. In Scotland, forensic science reports will conform to the usual joint report style, which allows prosecutors to make use of the routine evidence provisions of s. 280 of the Criminal Procedure (Scotland) Act 1995.

- Statement from the expert witness providing their opinion evidence as to the *capability* of the substance to have a psychoactive effect within the definition of the PS Act. For England and Wales, as well as complying with s. 9 of the CJA 1967, this statement must contain all matters required by Part 19 Criminal Procedure Rules (and related Case Management Directions). The analogous provision in Northern Ireland is Article 31 of the Criminal Justice (Evidence) (NI) Order 2004. In Scotland, evidence will be required from two expert witnesses in the form of a joint report in order to meet the requirements of corroboration.

- If the expert witness relies, in total or in part, on the *in*-vitro testing data, then a generic statement from those associated with the testing will be made available via CAST as follows:[11]

[11] Records will be maintained at all stages of the testing process

- A statement from the Technical Director of the laboratory carrying out the *in-vitro* testing, compliant in the relevant jurisdiction, covering the role and function of the laboratory, the quality procedures it has in place and an explanation of the technical process.

- A statement producing the *in-vitro* testing report, compliant in the relevant jurisdiction. In Scotland, evidence will be required in the form of a joint report in order to meet the requirements of corroboration.

Where relying on this *in-vitro* testing evidence, the statement from the expert witness will interpret the result from the laboratory. The conclusions in their statement will refer to the report provided by the laboratory and give an opinion that the results are consistent with the substance being capable of having a psychoactive effect, in accordance with the definition in PS Act and explain why.

Expert witnesses

CAST has identified a number of expert witnesses who will interpret the *in-vitro* testing results for evidential statements or otherwise provide an opinion of whether a substance is '*capable* of producing a psychoactive effect in a person who consumes it'.[12] CAST will facilitate the expert witnesses providing the evidential statements for the purposes of preparations for court order applications or charging. However, after these stages, it will be the responsibility of the law enforcement/CPS to engage the expert witnesses for the purposes of court proceedings.

Review

This guidance will be reviewed and updated as necessary. The ACMD will continue to provide independent scrutiny to ensure the forensic strategy continues to be founded on and supported by a robust evidence-base. The text provided by the ACMD in relation to how to demonstrate psychoactivity for the purposes of the PS Act will not be varied without further ACMD advice.

Home Office
Drugs and Alcohol Unit/Centre for Applied Science and Technology

May 2016

Home Office contact: psact@homeoffice.gsi.gov.uk

[12] Disclaimer : The Home Office does not recommend any experts listed through the maintenance of this list

Forensic Science Regulator
Overseeing Quality

PSYCHOACTIVE SUBSTANCES ACT 2016

TESTING OF SUBSTANCES FOR PSYCHOACTIVITY

I have considered the document "Specification for In-Vitro Testing of Substances" (version 2.0, dated 20 April 2016).

Based on advice from the Home Office Centre for Applied Science and Technology (informed by the expert panel) and from the Forensic Science Regulation Unit I am content with the Specification.

The Specification allows negotiations as to the details of the approach to testing.

If, as a result of the negotiations between the Authority (as defined in the Specification) and the Supplier referred to in section 3 of the Specification, the proposed testing regime differs significantly from what is set down in the Specification, I would expect to be briefed on the nature of the changes and their potential impact prior to the regime being approved or testing proceeding.

Dr Gillian Tully
Forensic Science Regulator

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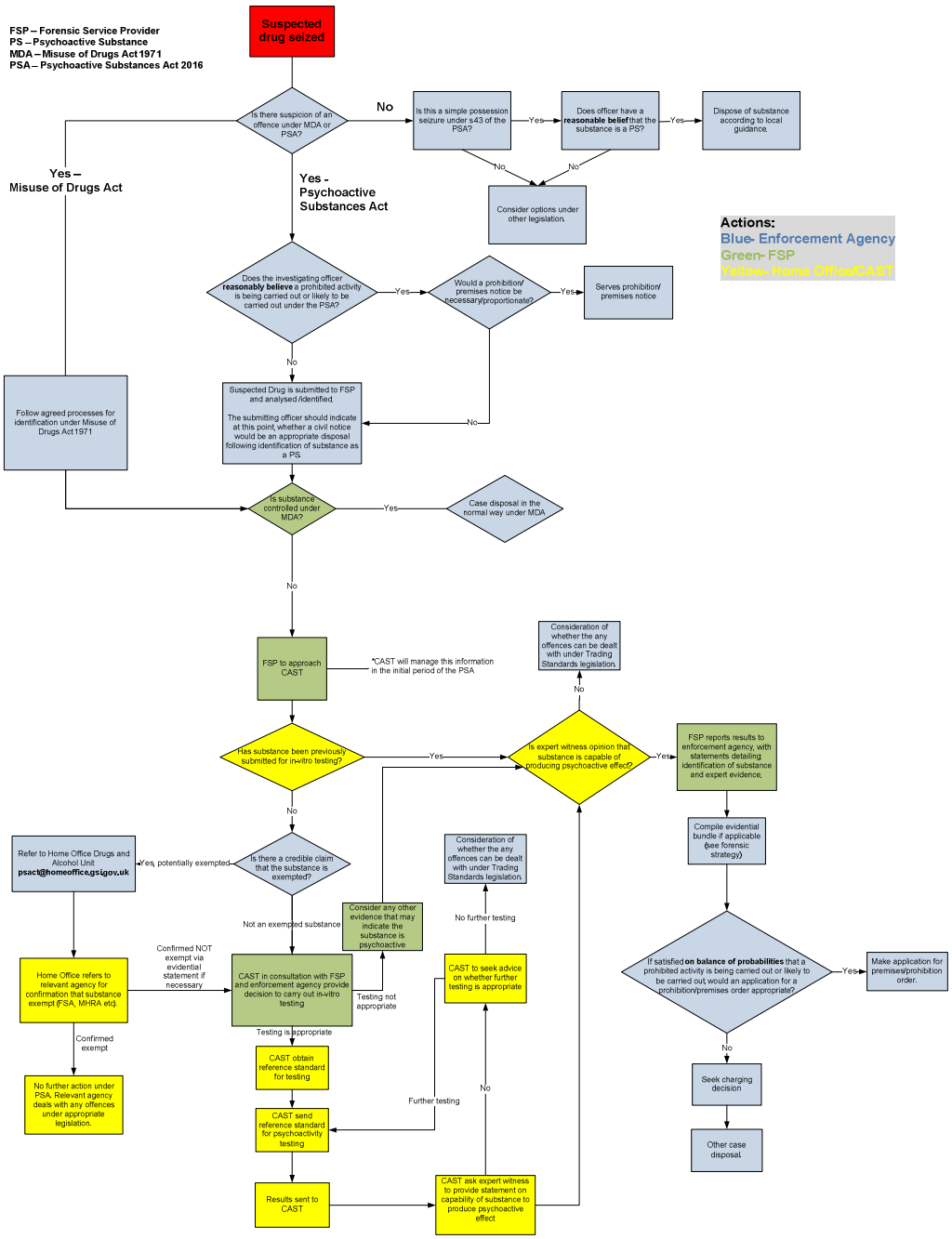

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