How the Controlled Substance Compliance & Shipping Expert Community is making real world changes!

Key Information

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Sponsors/partners

To join the steering committee, we ask for a $7K yearly contribution.

Recently, we have also:

Responded to the DEA's Controlled Substances Destruction Alternatives to Incineration (ANPRN) proposed rule changes (March 2024)

DEA-2023-0148

R&D companies working with controlled substances must adhere to strict regulations to ensure compliance. This is a costly and time-consuming task not eased by the complexity of regulations. Non-compliance has severe consequences for pharmaceutical companies, including fines, legal liabilities, reputational damages, and potential loss of licenses or permits.

An unprecedented change

In 2016 an amendment to Misuse of Drugs changed legislation (Fig. 1 and 2). This was due to a real rising problem with so-called 'legal highs'. However, the amendment resulted in large numbers of compounds (average number of ~100,000 in a major pharmaceutical company) being now caught under this act, impacting R&D operations both inside and outside the UK.

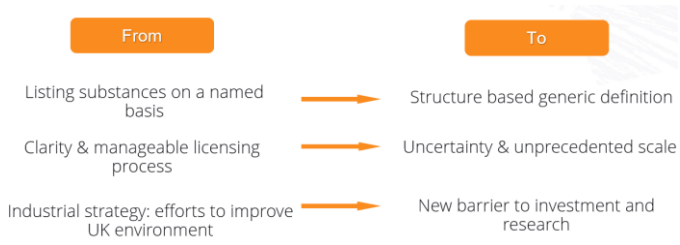


Figure 1. 2016 MDA amendment.

This was an issue too big for one single pharma company to tackle, but ideal for the Pistoia Alliance's CSCS group which worked with partners (RSC, ABPI, BPS, industry & CROs) on an end-to-end research exemption solution. In 2017, the ACMD put forward a new generic definition suggested by the CSCS group, which was approved by the UK parliament in 2019 (Fig. 3 and 4). The new generic resulted in a decrease in R&D controlled substances by 90% (Chemchecker and CS2) freeing up companies from the burden of unnecessary Schedule 1 constraints. This enables worldwide research to be carried out more easily. The collaborative approach and expertise of the Pistoia Alliance's CSCS expert community makes it an ideal platform for communicating technical advice and advocating change to governmental organizations.

What are generics?

Generics categorize drugs into broader groups based on their chemical structures, potential for abuse and medical use. This allows regulators to control a wide range of substances without having to specify specific chemical compounds or brand names.

The Misuse of Drugs Act 1971

The primary legislation governing controlled substances in the UK is the Misuse of Drugs Act 1971 (MDA). The UK government reviews drug classifications through processes such as the Advisory Council on the Misuse of Drugs (ACMD), which provides recommendations on drug policy.

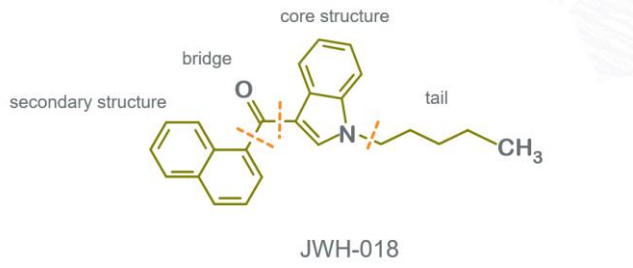


Figure 2. The Amendment made any compound (not being ***clonitazene, etonitazene, acemetacin, atorvastatin, bazedoxifene, indometacin, losartan, olmesartan, proglumetacin, telmisartan, viminol, zafirlukast)*** structurally related to 1-pentyl-3-(1-naphthoyl)indole (JWH-018) a controlled substance.

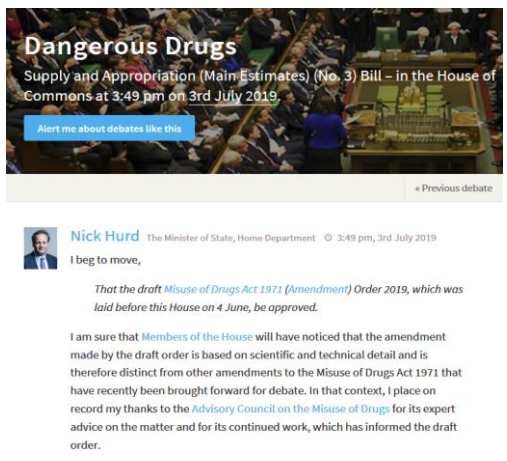
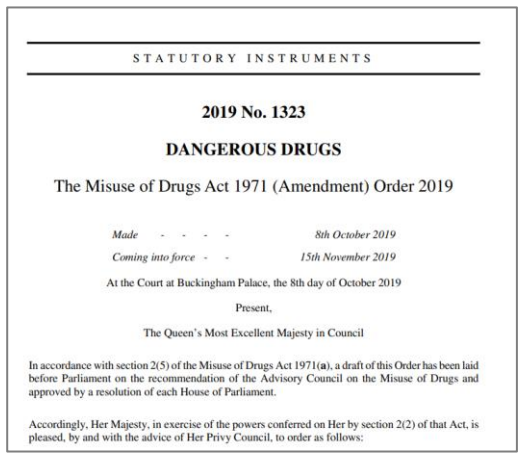


Figure 3


STATUTORY INSTRUMENTS

2019 No. 1323

DANGEROUS DRUGS

The Misuse of Drugs Act 1971 (Amendment) Order 2019

Made - - - - *8th October 2019*

Coming into force - - *15th November 2019*

At the Court at Buckingham Palace, the 8th day of October 2019

Present,

The Queen's Most Excellent Majesty in Council

In accordance with section 2(5) of the Misuse of Drugs Act 1971(**a**), a draft of this Order has been laid before Parliament on the recommendation of the Advisory Council on the Misuse of Drugs and approved by a resolution of each House of Parliament.

Accordingly, Her Majesty, in exercise of the powers conferred on Her by section 2(2) of that Act, is pleased, by and with the advice of Her Privy Council, to order as follows:

Figure 4

Generic Definition: A revision for synthetic cannabinoids.

2016: "…any of the sub-structures have been modified, and whether or not substituted in any of the linked sub-structures with one or more univalent substituents"

2019: "…any of the sub-structures have been modified, and whether or not substituted in any of the linked sub-structures with a benzyl or phenyl group and whether or not such compound is further substituted to any extent with alkyl, alkenyl, alkoxy, halide, haloalkyl or cyano substituents"

Pistoia Alliance's Controlled Substance Compliance & Shipping Expert Community

One of the Alliance's longest standing communities, the CSCS group aims to improve the understanding and interpretation of controlled substances and shipping legislation around the world.

If you would like to join the CSC & Shipping expert community, please get in touch with us CSCS@pistoiaalliance.org

www.pistoiaalliance.org

@pistoiaalliance