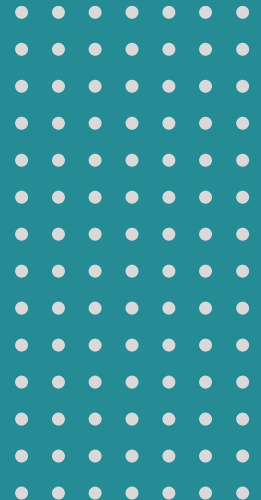


# Controlled Substance Compliance & Shipping Expert community

Improving the understanding of controlled substances and shipping legislation around the world

*Zofia Jordan, Consultant*  
*Nicolas Fur, Novartis*

*CSCS@pistoiaalliance.org*  
*Community manager [Birthe.Nielsen@pistoiaalliance.org](mailto:Birthe.Nielsen@pistoiaalliance.org)*



# Controlled Substance Compliance & Shipping Expert Community (CSCS)

Community manager  
[cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org)



## Problem Statement:

Legislation relating to Pharma R&D is changing rapidly; each change adds complexity and widens controls. Remaining compliant is an ever-growing challenge and consequences for breaches are severe. Compliance is also important in shipping. Customs, cold chains, dangerous goods and infectious material legislation all make R&D shipping complex.

## Value Proposition:

High levels of compliance are vital to credibility of and public trust in life science R&D. The CSCS Expert Community provides a forum for Compliance professionals, researchers, compound and shipping managers to share best practices and update their awareness of new legislation.

## Project Member:

The expert communities are made up of pharmaceutical companies and specialist software providers, sharing their knowledge and experiences on a voluntary basis.

## Project champions:

[Nicolas Fur & Ania Hajdukiewicz](#), Novartis, (Shipping)  
[Jessie Bin Song](#), Merck, (Controlled Substance Compliance)

## Steering Committee:

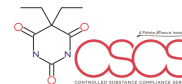


\$7K per year ensures a seat on the Steering Committee



## Project Deliverables:

- Round Table Discussions and Seminars
- Discussion and Collaborations with Expert Speakers, independent and quasi-judicial monitoring bodies





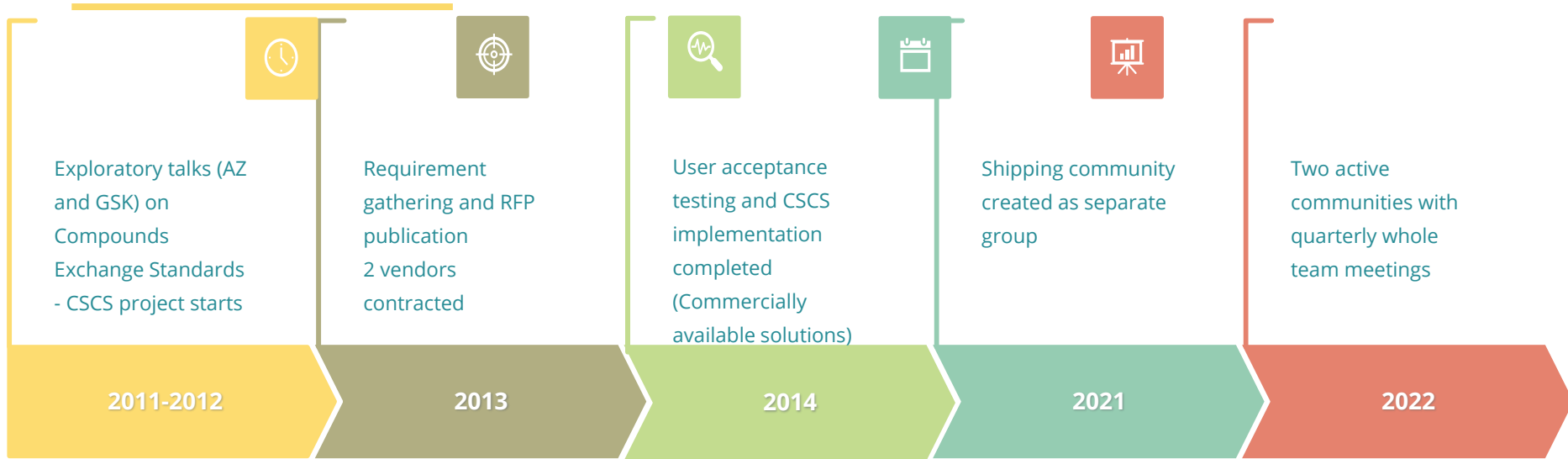
# Agenda

- How do the community operate
- CSC activities: communicating with regulators
- Shipping group: activities & call for input

Collaborate.  
Innovate.  
Educate.  
London 2024



# CSC & Shipping History



## Pre-project

An Expert System combined with a Controlled Substance Knowledgebase to determine if a substance is controlled

## Project Process

Chemaxon and Patcore: Compliance Checker  
Scitegrity: CS2

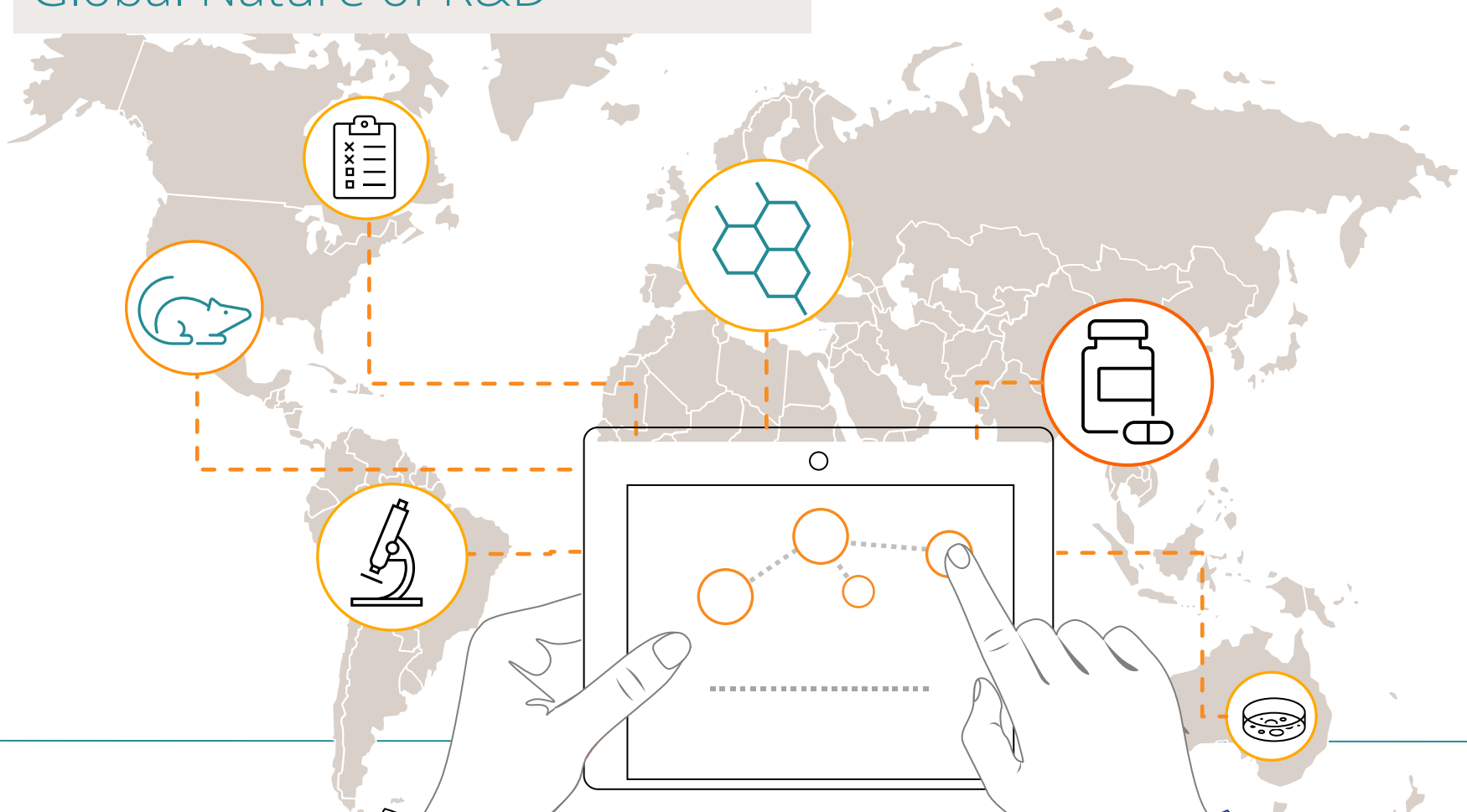
## 2 Expert Communities

>20 members from different pharma companies

# CSC - Mission

The Community focuses on tackling the challenges we face, developing solutions, communicating with regulators, and learning from each other to stay current and compliant with legislations governing controlled substance activities.

# Global Nature of R&D



# Myriad of legislation

## Controlled Substances Act

United States anti-drug law

The Controlled Substances Act is the statute establishing which the manufacture



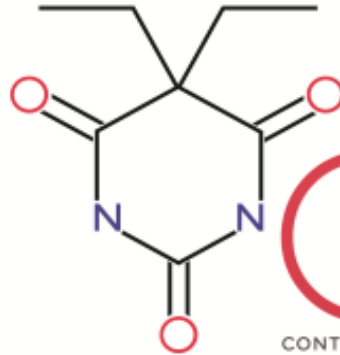
## German Federal Narcotics Act

Drug laws in Germany are covered by the German Federal Narcotics Act <sup>1 2 3</sup>. The act defines

## Misuse of Act 1971

UK legislation

The Misuse of Drugs Act of the Parliament in line with t



## Federal Agency for Medicines and Health Products

Belgian government agency



The Federal Agency for Medicines and Health Products in Belgium is responsible for new medication in Belgium. Xavier De Cuyper is General

## Arrêté du 22 février 1990 fixant la liste des substances classées comme stupéfiants

📅 Dernière mise à jour des données de ce texte : 23 mai 2021

NOR : SPSM9000498A

▸ [Accéder à la version initiale](#)



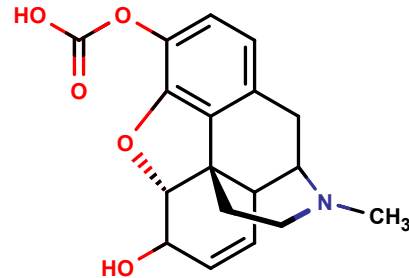
# It was all going so well

In the past:

Legislation was based around specific structures and some small generic examples.

Examples has to be interpreted and transformed from legal wording into scientific nomenclature to be useful,  
i.e. words into chemical structures

Morphine





# ACMD Report

Addresses 'Third Generation' synthetic cannabinoids  
An expanded generic definition...

'Simply increasing the number of generic controls to cover the broad range of psychoactive cannabinoid structures which are being identified using a similar approach to the existing controls **would require an extremely long list** of additional paragraphs. It is therefore proposed to adopt a different approach, based on defined modifications of a 'model' compound, 1-pentyl-3-(1-naphthoyl)indole ('JWH-018')

<https://www.gov.uk/government/publications/third-generation-synthetic-cannabinoids>

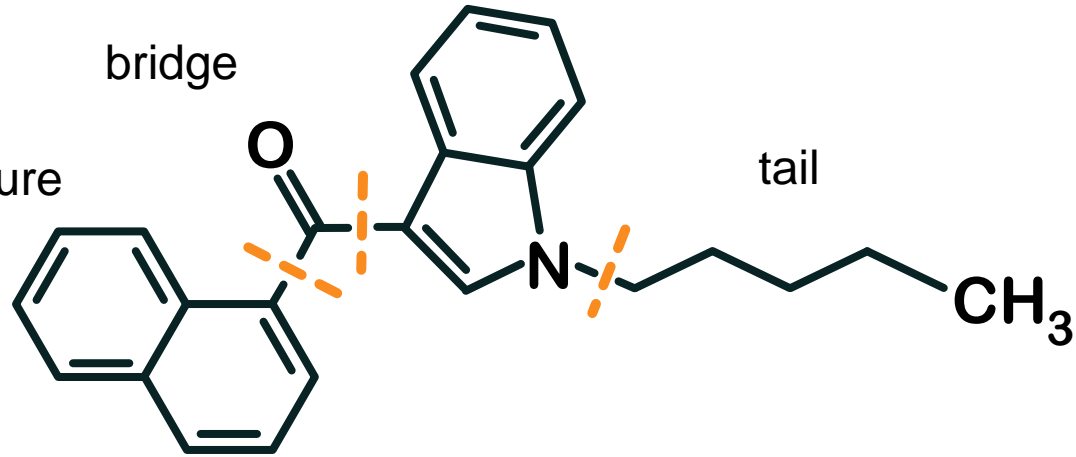
\* ACMD: Advisory Council on the Misuse of Drugs

core structure

bridge

secondary structure

tail



JWH-018



# An Unprecedented Change

From

Listing substances on a named basis



To

Structure based generic definition

Clarity & manageable licensing process



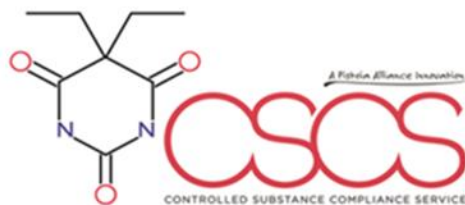
Uncertainty & unprecedented scale

Industrial strategy: efforts to improve UK environment



New barrier to investment and research

# Tackling the Issue: Working with our Partners



We are a global  
innovation in

Controlled Substance Compliance & Shipping Expert Community

barriers to

**The Association of the  
British Pharmaceutical  
Industry**



**BRITISH  
PHARMACOLOGICAL  
SOCIETY**



# The House of Commons and the House of Lords



**Nick Hurd** The Minister of State, Home Department

I beg to move,

*That the draft [Misuse of Drugs Act 1971 \(Amendment\) Order 2019](#) be approved.*

I am sure that [Members of the House](#) will have noticed that the draft order is based on scientific and technical advice and is therefore distinct from other amendments to the Misuse of Drugs Act which have recently been brought forward for debate. In this regard, I record my thanks to the [Advisory Council on the Misuse of Drugs](#) for its advice on the matter and for its continued work, which has been invaluable.

---

STATUTORY INSTRUMENTS

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**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:

---

**971 (Amendment) Order 2019**

[Share](#)

**15 July 2019**  
Volume 799

Misuse of Drugs Act 1971 (Amendment) Order 2019.

Parliamentary Scrutiny Committee

**Business Williams of Trafford (Con)**

relates to the Misuse of Drugs Act 1971 in that it is based on

changes to scientific and technical detail in existing legislation and does not introduce further controls on compounds

# DEA's controlled Substances Destruction Alternatives to Incineration: Responding to proposed rule changes



**VIA ELECTRONIC SUBMISSION**

March 26<sup>th</sup>, 2024

Drug Enforcement Administration  
Attn: DEA Federal Register Representative / DPW  
8701 Morrisette Drive  
Springfield, Virginia 22152

**Subject:           Comments to: Controlled Substance Destruction Alternatives to Incineration**  
RIN 1117-AB84/Docket No. DEA-1144

TO THE ATTENTION OF DEA FEDERAL REGISTER REPRESENTATIVE/DPW



# Shipping community - Mission

Our commitment is to participate in speeding up drug discovery effort by shipping in an efficient and compliant way while dealing with a constantly evolving regulatory space and high material variety.

# Mutual Goal: Cycle time and Quality

## Key parameters

- ❖ Temperature restrictions
- ❖ Compliance aspects
  - ❖ Compliance checks, classification
  - ❖ Declaration and permits: Customs, FDA, HMRC, USDA, Fish and Wildlife, DEFRA, CDC
- ❖ Time to prepare and transport the shipment
- ❖ Routing – Should/Must use preferred LSP
- ❖ Incidents - Requestor, Shipper, Carrier





# Compliance considerations

## Key parameters

All shipments have to be in compliance with local and international regulations.

- ❖ HS Code
- ❖ INCO Terms
- ❖ Valuation
- ❖ Permits and Licenses
- ❖ Country of Origin
- ❖ Denied Party Screening
- ❖ Dangerous Goods
- ❖ Material Description (a catch all element)



# How do we reduce those Barriers?

Goal: Materials arrive in a timely manner and in the same condition as when the shipment left the site of departure

Challenges: Nature of the materials produced for research and evolving requirements

## Reducing Barriers:

- Awareness to the Process to the People who Contribute to the Process
- Awareness to the Compliance Elements Critical to the Process
- Voice your needs and problems



# CSC & Shipping Activities

## Enhancing best practice

### Discussions and speaker program

(PhRMA)Pharma  
research CS  
Regulation  
landscape

Inventory  
management  
system  
(Biovia)

James Felman  
Defending  
analogue cases

Roundtable  
discussions  
and Bench-  
marking  
with  
members

Biocair - Brexit

Specialty logistics  
service providers

US section 301  
China tariffs

Brexit 2022

INCB  
Trend precursors  
and industry  
collaboration

Suspicious order  
Monitoring  
(SOM)/ IQVIA

Licenses and  
inspections in  
different  
countries

Colin Clarke  
(Avantor),  
international  
shipping

Changes to HS  
nomenclature and issues

Dangerous Goods (DG),  
road and Air. DGSA

### Horizon scanning, encourage input to public consultations

Fentanyl  
generic and US  
GAO  
consultation

Barriers to  
Research. UK  
ACMD

Monitoring  
legislative changes  
(Scitegrity,  
ChemAxon)

HS  
Classification  
tools

DEA's  
Alternative to  
incineration  
response

# Call to Action – Pistoia Alliance R&D Shipping Expert Community organizing a focus group

- **Objective:** Discuss obstacles in R&D Shipping Coordination IT Systems
- **Scope:** Covers Sample Management/Compound Management, Clinical, and Lab Samples
- **Participants:** All Pharma R&D including 3rd party CROs and CMOs
- **Challenges:** Lack of off-the-shelf solutions, decentralized approach leading to inefficiencies
- **Opportunity:** Collaborate to identify solutions



**Unlocking Efficiency and Compliance: Join the new Shipping Tooling Focus group:**

R&D units navigate a maze of shipments monthly, spanning domestic and global territories. From sample management to clinical and lab samples, the complexity is immense.

In the absence of tailored solutions, pharmaceutical companies resort to in-house systems to oversee the coordination, trade, and dangerous goods aspects of this process. This decentralized approach often leads to inefficiencies, potentially exacerbating trade compliance and safety risks associated with consignments.

**Collaborate for change:**

Your insight is invaluable. Together, let's shape a safer, more efficient shipping landscape. Reach out to [cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org) and be part of developing the requirements for a new tooling solution.

# How can I join?

- A company must be a member of the Pistoia Alliance
- Each company may send as many participants as they wish to the meetings
- You can join one or both expert communities
- Details on how to join: [cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org)



**Key Information**  
 Chair: CSCS Jesse Bin Song  
 Chair Shipping: Jack DeCicco/Helen Fox  
 Project manager: Birthe Nielsen  
 Contact for CSCS@pistoiaalliance.org  
**Specialist Expert Community**  
 To improve the understanding and representation of controlled substances and shipping legislation around the world

**Sponsors/partners**



Join the Pistoia Alliance Controlled Substance Compliance & Shipping Expert Community. If you would like to join the CSCS & Shipping expert community, please get in touch with us: [cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org)

## Controlled Substance Compliance & Shipping Expert Community

**What we do**

High levels of transparency are vital to maintain public trust in its licensed field. The work of the Controlled Substance Compliance & Shipping expert community helps its members up-to-date with current developments in best practice, legislation and regulations.

Controlled substance legislation has changed rapidly in recent years and legislation related to social, legal and economic functioning compliant in this environment is an ever-changing challenge, and consequences for breaches can be severe.

Cross-border shipping is also a very dynamic and regulated environment and it is very closely with aspects of Controlled Substance Legality. Pharma companies must ensure shipments are fully compliant with both national and international requirements. Mistake could deliver or rejected shipments which in turn have negative impact on pharmaceutical R&D timelines.

This long standing expert community focuses on tackling the challenges and legal, economic issues, communicating with regulators and liaisons from each other to stay current and compliant with legislation governing controlled substances and shipping activities.

**Unlocking Efficiency and Compliance in the New Shipping Testing Focus group**

R&D can't navigate a maze of shipments resulting in delays, cost and quality bottlenecks. From sample management to clinical and lab samples, the complexity is immense.

In the absence of tailored solutions, pharmaceutical companies must try to make sense of the complex, multi-dimensional aspects of international, trade, and management across aspects of the process. These dimensional aspects contribute to inefficiencies, potentially increasing trade compliance and safety risks associated with consignments.

**Outlook for change:**  
 Your insight is invaluable. Together, let's shape a safer, more efficient shipping landscape. Reach out to [cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org) and let us understand the requirements for a new testing solution.

**Who should join?**

The expert communities are made up of major pharmaceutical companies and specific industry providers. The community provides an open and safe environment for members to communicate and share expertise with each other. If you would like to join the controlled substance and shipping expert community, please get in touch with us: [cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org)

**Recent topics include:**

**Changes to US nomenclature & resulting issues**  
 Barries is research. The US industry Council on the Misuse of Drugs recommends to change the nomenclature for research organizations on products which are used for the synthesis of controlled substances.

**The International Narcotics Control Board on levels and risk of precursors and collaboration with drug and international governments to control their use and the 1988 Convention and Equipment control in 8th drug manufacturing.**

**Pharmaceutical Research and Manufacturers of America (PhRMA) on the existing activities of US Controlled Substance Regulations including conflict between state and federal laws.**

**Regulatory Order Meeting (ROM) ROMs presented the proposed changes in ODA regulation and comments received by the ODA.**

**Specialty logistics service providers. Who's Who: The 11 shipping providers, role and responsibilities and the types of shipment handled by these service providers.**

**Inventory management systems. ROMs presented their solution for inventory management, focusing on the controlled substances application. Members benchmarked the inventory management processes.**

**Inspections and audits. Regulatory inspectors, internal audit programs, formal applications and results. This resulted in the formation for the group of a regulatory for ODA with a focus of a level 1 or level 2 threshold for major law violations.**

**Manufacturing strategy. The group undertook a large exercise on how pharma manages logistics and manufacturing strategy.**

**Dangerous Goods (DG) Transportation of DG by road and air. The group discussed the role and responsibilities of the DG Safety Advisor (DGSA), including specific countries requirements.**

**ODAs Controlled Substances Distribution Alternatives to improve and reduce the risk to ODA and proposed rule changes (MRF 2024, 19A, 19B, 2023-01-48) on destruction of controlled substances.**



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



**Key Information**  
 Chair: CSCS Jesse Bin Song  
 Chair Shipping: Jack DeCicco/Helen Fox  
 Project manager: Birthe Nielsen  
 Contact us: [cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org)  
 This poster has been prepared by: Zofia Jordan, Ian John, Birthe Nielsen

**Sponsors/partners**



Join the shipping community we ask for a 47% yearly contribution.

**Recently, we have also:**

Responded to the ODA's Controlled Substance Destruction Alternatives to Improve and Reduce the Risk to ODA (proposed rule changes) (March 2024)

ODA 2023-01-48

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 2014 an amendment to Misuse of Drugs changed regulation (Fig. 1 and 2). This was due to a real world problem with so-called 'legal high'. However, the amendment resulted in large numbers of compounds. Average number of 1000000 in a major pharmaceutical company being now caught under this act, impacting R&D operations both inside and outside the UK.



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 (MSD, AstraZeneca, Pfizer, Novartis) and endorsed research examination solution. In 2017, the ACOMD 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 50% (ChemAxon and CSCS) leaving up companies from the burden of unnecessary Schedule 1 compounds. This valuable contribution remains 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.



**Pistoia Alliance's Controlled Substance Compliance & Shipping Expert Community**  
 One of the Alliance's largest standing communities, the CSCS group aims to improve the understanding and representation of controlled substances and shipping legislation around the world.

If you would like to join the CSCS & Shipping expert community, please get in touch with us: [cscs@pistoiaalliance.org](mailto:cscs@pistoiaalliance.org)

**What are generics?**  
 Generics categorize drugs into broader groups based on their chemical structure, potential for abuse and medical uses. 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 revised drug classifications through regulations such as the Advisory Council on the Misuse of Drugs (ACMD), which provides recommendations on drug policy.

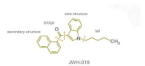


Figure 1: The amendment made any controlled drug being Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5, Schedule 6, Schedule 7, Schedule 8, Schedule 9, Schedule 10, Schedule 11, Schedule 12, Schedule 13, Schedule 14, Schedule 15, Schedule 16, Schedule 17, Schedule 18, Schedule 19, Schedule 20, Schedule 21, Schedule 22, Schedule 23, Schedule 24, Schedule 25, Schedule 26, Schedule 27, Schedule 28, Schedule 29, Schedule 30, Schedule 31, Schedule 32, Schedule 33, Schedule 34, Schedule 35, Schedule 36, Schedule 37, Schedule 38, Schedule 39, Schedule 40, Schedule 41, Schedule 42, Schedule 43, Schedule 44, Schedule 45, Schedule 46, Schedule 47, Schedule 48, Schedule 49, Schedule 50, Schedule 51, Schedule 52, Schedule 53, Schedule 54, Schedule 55, Schedule 56, Schedule 57, Schedule 58, Schedule 59, Schedule 60, Schedule 61, Schedule 62, Schedule 63, Schedule 64, Schedule 65, Schedule 66, Schedule 67, Schedule 68, Schedule 69, Schedule 70, Schedule 71, Schedule 72, Schedule 73, Schedule 74, Schedule 75, Schedule 76, Schedule 77, Schedule 78, Schedule 79, Schedule 80, Schedule 81, Schedule 82, Schedule 83, Schedule 84, Schedule 85, Schedule 86, Schedule 87, Schedule 88, Schedule 89, Schedule 90, Schedule 91, Schedule 92, Schedule 93, Schedule 94, Schedule 95, Schedule 96, Schedule 97, Schedule 98, Schedule 99, Schedule 100.

Generic Definition a solution for synthetic controlled substances.  
 One of the sub-structures has been modified, and either not substituted in any of the final sub-structures with one or more substituents.  
 2019 - Large of the sub-structures have been modified, but neither of the substituted or unsubstituted sub-structures with a total of 1000000 sub-structures or more substituted or unsubstituted with only one or more substituents.

**Pistoia Alliance**  
 www.pistoiaalliance.org  
 @pistoiaalliance



# Questions

