



# CSCS Expert Community

*Improving the understanding of controlled substance legislation around the world.*

CSCS Expert Community lead – Andreas Schumacher

CSCS Expert Community manager – Claire Bellamy

# CSCS Expert Community

The Controlled Substance Expert Community provides a forum for industry compliance officers and compound managers to share best practice in controlled substance compliance and update their awareness of new legislation.

Our members include major pharma and specialist software providers.

## Steering Committee



## Project Members

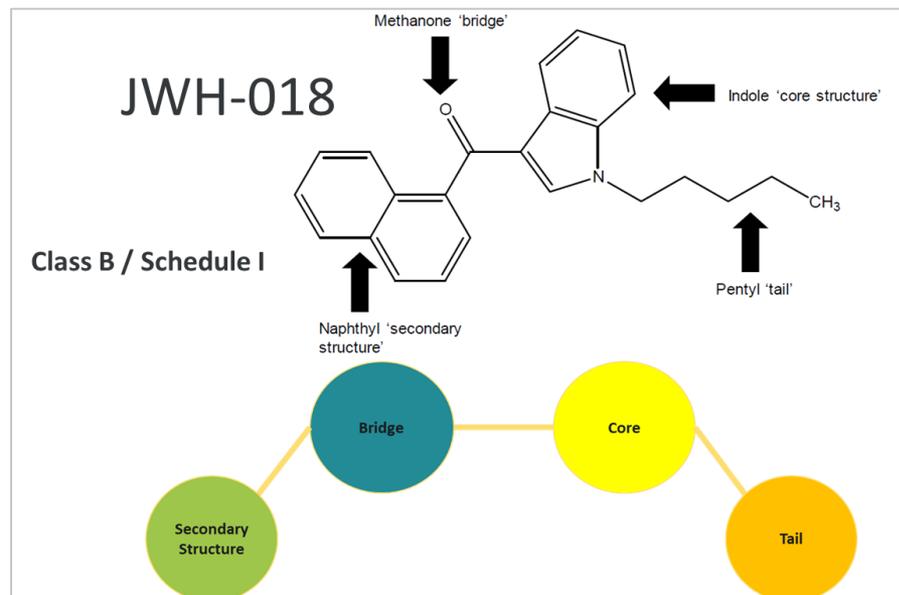
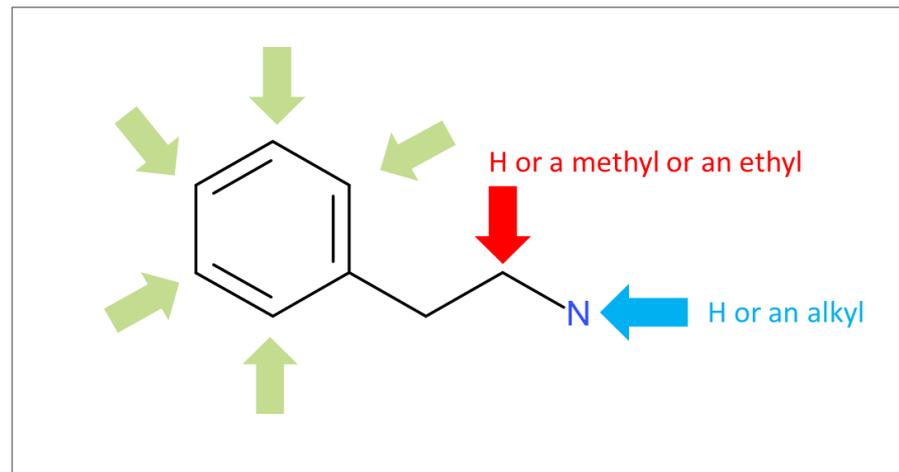


# Why is this needed now?

Legislation is changing rapidly and it has become much more complex to stay compliant.

Markush structures were widely adopted in the 2000s and define an area of chemical space. There is ambiguity in many definitions, but this approach generally results in a manageable number of controlled substances.

Recently countries have started to define super-generics. These capture significantly more compounds in pharma libraries and are much more difficult to interpret



# How does the group work?

Whole team meetings with invited speakers are held on-line quarterly. Members are widely spread across Europe, North America and China. Extra meetings are occasionally called if needed.

The steering committee is made up of a single representative from each organisation. It meets quarterly, to steer the group's activities and hold more detailed discussions.

Andreas Schumacher (Novartis) is the chair of the group and oversees the strategy.

Claire Bellamy is the coordinator.

# CSCS Activities

## Enhancing best practice

Previous discussions and speaker program

The opioid crisis in the US: proposals and policy considerations - PhRMA

Chinese controlled substance legislation – Millipore-Sigma

Tariff coding - Scitegrity

International Drug regulation. - Simon Elliot, WHO

US drug regulation, an expert witness perspective - Prof DeCaprio

## Regulators

Horizon scanning, encourage input to public consultations

### Sponsor and status

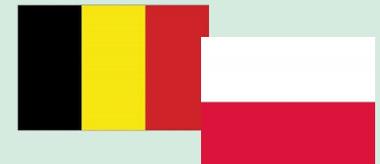
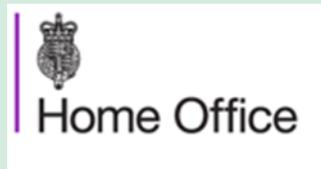


**John Katko**

Sponsor. Representative for New York's 24th congressional district. Republican.

Monitoring progress of bills such as SITSA

UK Misuse of Drugs Act amendment 2016



Monitoring legislative changes e.g. Belgium and Poland

# Confluence project discussion area

- Useful links to legislator websites
- Discussions
- Subgroup output
- Interesting news items

Confluence Spaces People Create

CSCS

Blog

PAGE TREE

- [Links to legislators websites](#)
- Legislation Review
  - › Completed Discussions
  - › UK - Ether and Ester Derivatives of Co
  - USA - Barbituric acid derivatives - Con
  - USA - Positional isomers
- › China Subgroup
- › South America Subgroup
  - Argentina
  - Brazil
  - Columbia
  - Mexico
  - Resources

CSCS Home

Created by Richard Holland, last modified by Claire Bellamy on Jul 06, 2015

Welcome to the CPCS Wiki Space. This area will contain the latest project news and allow us all to post comments and interact with the latest activities.

Welcome to the Controlled Substance Compliance Service Expert Community

The outcome of discussions of this group are reflected in the following products

- [ChemAxon/Patcore - Compliance Checker](#)
- [Scitegrity - Controlled Substances Squared](#)

Documents for this project can be found on the [Google Drive](#)

Public information is available on the [CSCS Website](#)

Legislation Alert

This area contains new or changed legislation that the CSCS Expert Community thinks warrants discussion and is not comprehensive alerting service.

Please send Claire any new items you think should be included and please comment on anything here.

[Removal of \[123I\]lofupane From Schedule II of the Controlled Substances Act](#)

Claire Bellamy posted on Sep 16, 2015

# How do I join?



A company must be a member of the Pistoia Alliance.

Participating companies are requested to contribute a subscription. At present, this is set at \$6K per year. It is used for coordination costs and face-to-face meetings.

Each company may send as many participants as they wish to the meetings.

Details of how to join are available from  
[claire.bellamy@pistoiaalliance.org](mailto:claire.bellamy@pistoiaalliance.org) or  
[john.wise@pistoiaalliance.org](mailto:john.wise@pistoiaalliance.org)



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