CSCS Expert Community: The Changing Landscape of Drug Controls

Key Information

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Goal of the Expert Community

To improve the understanding and interpretation of controlled substance legislation around the world.

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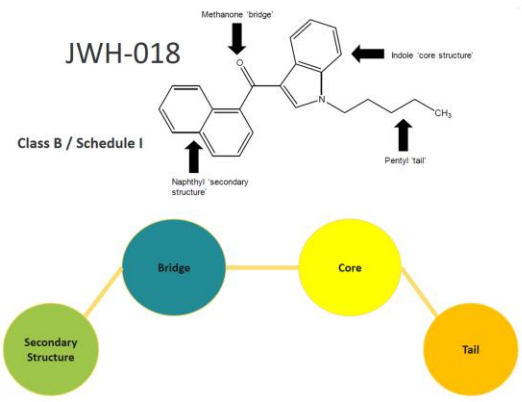
Introduction

Drug controls are a key compliance issue for companies that handle large numbers of research compounds. Legislation has become more complex and changes are being made more frequently. The Controlled Substance Compliance Expert Community brings together specialists from across the industry to discuss areas of uncertainty and enhance best practice.



How things have changed

In the beginning...

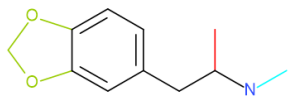
International agreements to control drugs were put in place in the 1960s

1961	Single Convention on Narcotic Drugs	'Yellow List'	e.g. Heroin
1971	Convention on Psychotropic Substances of 1971	'Green List'	e.g. MDMA
1988	United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	'Red List'	e.g. Acetic Anhydride

These lists were based on named compounds and their salts, stereoisomers, esters and ethers.

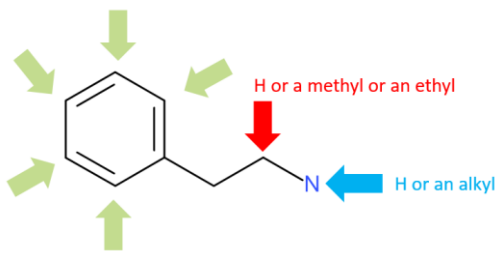
1970s - Response to chemical modification

Synthetic compounds start being developed such as MDMA.



MDMA

In response, a new class of generics appear in legislation. A core is specified that can be substituted in multiple places.



Compliance is no longer a matter of checking against a list but requires a sophisticated structural check.

2010 onwards - Explosion of illegal synthesis

Shops appear that sell 'legal highs', synthetic drugs are specifically designed to avoid the law. Countries start to legislate in a much more generic way, with bans based on biological effect or structures that are made of multiple component parts.

Belgium, Germany, Poland, UK and the US have enacted laws containing super-generics in the past 2 years. Some include research exemptions, but some of this legislation makes compliance more complex.

The UK, for example, brought in such a broad definition of synthetic cannabinoids in 2016, that it encompassed a significant percentage of a typical pharma compound bank. It also affected established marketed medicines and in-flight clinical trials.

After consultation with the CSCS Expert Community and others, the law was amended in 2019 to reduce the numbers of non-psychoactive compounds affected and focus controls on the intended target.

Expert Community

The increasing complexity and scope of controlled substance legislation mean it is vital to understand when legislation is about to change and assess the impact on your organization. The penalties for incorrect compliance are significant: ranging from large fines to loss of reputation and potentially loss of license to operate.

The expert community provides a forum to discuss best practices with your peers so you can build your understanding, plan and put into practice the necessary changes to your internal processes in good time.

The community runs a range of activities and discussions, and members can bring questions to the group. External speakers are invited to present on topics of interest and in-depth work is undertaken by sub-teams when required.

Conclusion

The legislative landscape has changed beyond recognition and controlled substance legislation is more complex and rapidly changing than ever before. The CSCS Expert Community brings together experts in a network that aims to improve practice and works together to bring clarity to areas of uncertainty.

References

www.CSCS-Experts.org

Taylor, Daniel, et al. (2015), "*The Pistoia alliance controlled substance compliance service project: From start to finish.*" Drug Discovery Today, Volume 20, Issue 2, pp 175-180.

Pistoia Alliance: Lowering barriers to R&D innovation

The Pistoia Alliance is a global, not-for-profit alliance of life science companies, vendors, publishers, and academic groups that work together to lower barriers to innovation in R&D.

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