

Does this affect us?

Our experience working with chemical suppliers and pharma companies show a compound collection of 1M compounds will likely have several thousand regulated or controlled substances from...

- Library compounds from previous programs that are now controlled (e.g CB1, Opioid, many pain targets, sleep disorders programs, anti depressants).
- “Collateral damage” e.g not addictive, not even a CNS target, but caught by a generic description so must be treated as controlled
- Some common building blocks can chemicals also be regulated as they are easily convertible into Controlled Substances or can be used for military applications (EU Military dual use lists, US Commerce Control Lists and International Traffic in Arms Regulations etc)

Remember - for most of these targets the chemical space is controlled – not just the approved drug, so all the library series etc

We have assisted several Pharma in this respect – it can and does happen. De risk early! It being in a clinical trial will not exempt it, get your licence sorted early and work with legislators for an exemption early on

Requires record keeping, especially when importing / exporting or selling in bulk

Ok, so that might be us - but this can't apply for a few mg's for Research Purposes?

- A common held belief that's almost always wrong
- In general there are no exemptions based on research use or small amounts, even milligrams
- Usually when there exemptions, you will still require some form of licence and cannot supply the compounds to anyone else who does not have the licence
- This especially applies when shipping compounds to customers or collaborator on different sites

But the laws don't vary much between countries do they?

Yes, they vary greatly. Each European country has its own laws. The USA and many Europe in general take very different approaches in defining what chemical space is controlled

Country	Regulated or controlled chemicals in the ACD*
United Kingdom	53,336
Belgium	47,584
Ireland	31,409
Poland	30,474
Switzerland	30,284
United States of America	28,006
Denmark	23,813
France	8496

*The ACD (Available Compounds Directory) as of January 2017 - legislation as of February 2020. 11.7M compounds in total.

Suppliers – what are you selling?
Purchasers – what are you buying?

Both need licences, know what it is and declare it

Ok, but regulators will turn a blind eye won't they?

- You are expected to self police and the impact can be severe if you do not put appropriate controls in place.
- The Opioid and Cannabinoid crisis combined with the ease of internet ordering means increased interest by regulators and law enforcement on suppliers

2017 - Pharma A had to apply for emergency licencing to continue a cancer clinical trial after finding the lead molecule fell under a newly enacted piece of UK Controlled Drug legislation.
The fact it was a potential cancer treatment did not exempt it

2018 - Chemical supplier X which supplies research companies and universities in the USA was recently order to shut for several weeks after the DEA found it was able to order milligram amounts of US scheduled substances.

Can I just do this with a small list of CAS numbers or names?

- I'm afraid not – it needs to be done structurally and computationally.
- Even for a single named substance you will generally find legislation covers all ethers, esters, salts and stereoisomers. This enumerates into hundreds or thousands of possible names and number, many never before synthesised
- How many way can you name a single molecule?
- Most countries now control chemical space – there are no specific CAS numbers or chemical listed!

(c) any compound (not being methoxyphenamine or a compound for the time being specified in sub-paragraph (a) above) structurally derived from phenethylamine, an N-alkylphenethylamine, a-methylphenethylamine, an N-alkyl-a-methylphenethylamine, a-ethylphenethylamine, or an N-alkyl-a-ethylphenethylamine by substitution in the ring to any extent with alkyl, alkoxy, alkylendioxy or halide substituents, whether or not further substituted in the ring by one or more other univalent substituents.”

What about lists published by regulators?

- Some regulators like the DEA (US) and UK government publish [commonly encountered drugs lists](#).
- However these lists are by no means complete and accurate.
- They simply list common drugs of abuse and NOT everything under control
- They don't include different salts, ethers, esters, generic statements (see previous slide)
- Also when searching these by name you have to ensure you have exactly the same name as its listed on the site.
- A common compliance failing we find within companies is a false belief that name searching these lists alone leads to compliance