

A comparative study of the quality and performance of imported PoCT devices into the EU. Is regulation require to protect the EU market?

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Comparative study between PoCT device's manufactured in Asia and Europe

Aim of study:

To determine if cheap PoCT imports from Asia are manufactured to the same quality and present the same performance as those manufactured within the EU.

What do we mean by quality and performance?

1. To prevent drug abusers from performing 'work related' activities that might cause harm to themselves or others.
2. The testing process must produce highly specific and sensitive results, with a minimum of false positives and false negatives
3. The specificity and sensitivity of the test must be constant, i.e. each testing device must produce the same results given the same circumstances.
4. There has to be instrument quality control and manufacturing traceability.

Do all PoCT devices meet these criteria?

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Sample selection:

- 11 panel PoCT device's were obtained from 7 manufactures within Europe and 7 from Asia.
- 5 different manufacturing batches where obtained from each supplier.
- Selection was based on the cheapest published price.

What do we mean by quality and performance?



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drug test saliva/ thc marijuana drug rapid test kit/

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How were the device's tested:

- Standards were produced for each compound on the panel using synthetic urine. Standard concentrations equalled the reported detection threshold of the device plus 10%.
- The testing process was then conducted following the manufactures instructions for each drug on the panel on each device.
- Total number of tests = 15,400

Specificity and sensitivity of PoCT device's manufactured within the EU

Compound	Standard Concentration ng/ml (Urine)	Mean Sensitivity (%) n = 700	Mean Specificity (%) n = 700
D-Amphetamine	1000	100	100
Secobarbital	300	100	100
Oxazepam	300	100	100
Buprenorphine	10	100	100
Benzoylecgonine	300	100	100
Methadone	300	99	100
D-Methamphetamine	1000	100	100
D-Methylenedioxyamphetamine	500	100	100
Morphine	300	98	100
Nortriptyline	1000	100	100
11-nor-delta9-THC-9-COOH	50	96	100

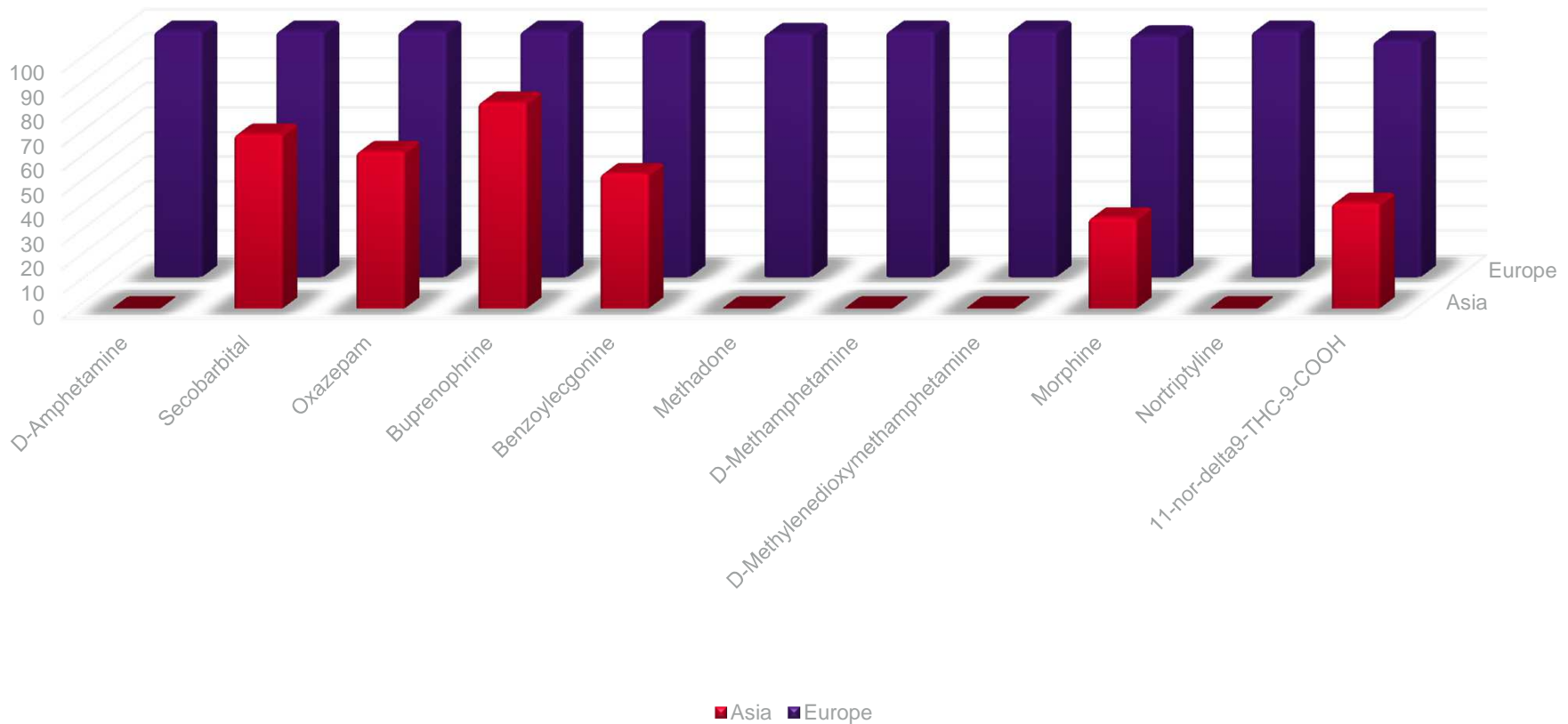
** Each PoCT device was tested 100 times per compound

Specificity and sensitivity of PoCT device's manufactured in the Asia

Compound	Standard Concentration ng/ml (Urine)	Mean Sensitivity (%) n = 700	
D-Amphetamine	1000	0	
Secobarbital	300	71	
Oxazepam	300	64	
Buprenorphine	10	84	
Benzoylecgonine	300	55	
Methadone	300	0	
D-Methamphetamine	1000	0	
D-Methylenedioxyamphetamine	500	0	
Morphine	300	37	
Nortriptyline	1000	0	
11-nor-delta9-THC-9-COOH	50	43	

Comparison between sensitivity of PoCT device's manufactured in Asia and Europe

Comparative sensitivity between Asian and European manufactured
PoCT device's

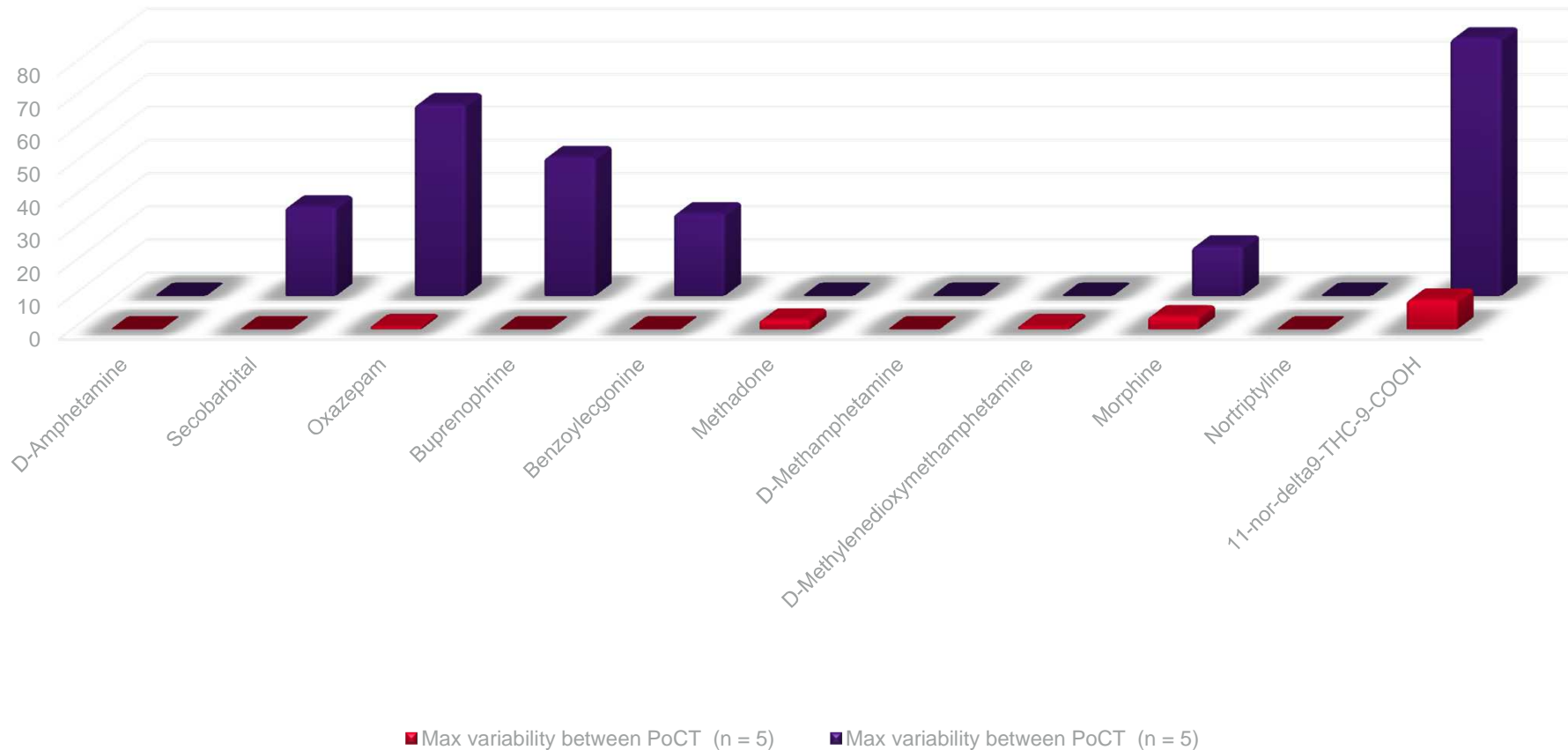


Comparison in inter-batch sensitivity of PoCT device's manufactured in Asia and Europe

Compound	Max variability between PoCT batch (%) n = 5	Max variability between PoCT batch (%) n = 5
	European origin	Asian origin
D-Amphetamine	0	0
Secobarbital	0	27
Oxazepam	1	58
Buprenorphine	0	42
Benzoyllecgonine	0	25
Methadone	3	0
D-Methamphetamine	0	0
D-Methylenedioxyamphetamine	1	0
Morphine	4	15
Nortriptyline	0	0
11-nor-delta9-THC-9-COOH	9	78

Comparison in inter-batch sensitivity of PoCT device's manufactured in Asia and Europe

Inter-batch variability in PoCT sensitivity



Traceability of PoCT device's

- All European devices were CE marked and clearly labelled with individual serial and batch numbers.
- 20% of the Asian products had a CE label.
- One Asian device was labelled as FDA approved although no record of the approval could be obtained.
- All devices had serial and batch numbers although inconsistencies cast doubt on their validity.

Do we need to worry about the quality of imported PoCT device's?

The European occupational health industry is based on trust!

- Occupational health companies within European companies are generally assumed to provide high quality products, advice and testing services.
- Testing results are believed to be valid by customers.
- Employees subject to testing also have a high degree of trust in the tests.
- Legal challenges are few and far between.

Why do we need to worry about the quality of imported PoCT device's?

Poor quality and / or counterfeit products removes trust.

Lack of trust could destroy the market!