Drug Status Report

**Drug**: Olanzapine related substances

A client requested the status of these olanzapine related substances.

**Drug Name Status**:
- I - 4-Amino-2-methyl-10H-thieno[2,3-b][1,5]benzodiazepine
- II - 2-Methyl-5,10-dihydro-4H-thieno[2,3-b][1,5]benzodiazepine-4-one
- III - 5-Methyl-2-[(2-nitrophenyl)amino]thiophene-3-carbonitrile
- IV - 1-Methylpiperazine
- V - 1-Chloromethyl-1-methyl-4-(2-methyl-10H-thieno[2,3b][1,5]benzodiazepine)piperazinium chloride
- VI - 2-Methyl-4-piperazinyl-10H-thieno[2,3-b][1,5]benzodiazepine
- VII - 4-(4-methylpiperazin-1-yl)-2-[(4-methylpiperazin-1yl)methyl]-10H-thieno[2,3-b][1,5]benzodiazepine
- VIII - 5-Amino-4-cyano-2-methylthiophene
- IX - 1-Fluoro-2-nitrobenzene

**Chemical Name**: The names above are the chemical names

**Chemical structure:**

![Chemical structures](image-url)
Molecular Formula: I - C₁₂H₁₁N₃S
II - C₁₂H₁₀N₂OS
III - C₁₂H₉N₃O₃S
IV - C₅H₁₂N₂
V - C₁₈H₂₄Cl₂N₄S
VI - C₁₆H₁₈N₄S
VII - C₂₂H₃₀N₆S
VIII - C₆H₄N₂S
IX - C₆H₄FNO₂

Pharmacological class / Application: Olanzapine related substances

International status:

US: These substances is not listed on the schedules to the US Controlled Substances Act.

United Nations: The substances are not listed on the Yellow List - List of Narcotic Drugs under International Control nor on the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Item 18 of Schedule IV is, “Benzodiazepines, their salts and derivatives”. SOR/99-371¹, the amendment that excluded olanzapine (subitem 34) from item 18 of Schedule IV recognized that, “Olanzapine belongs to a class of drugs known as benzodiazepines.” Substances I, II, V, VI, VII are benzodiazepines and therefore included in the benzodiazepine class of substances.
Substances III, IV, VIII and IX are not benzodiazepines; they are also not similar to other substances listed on the schedules to the CDSA.

Recommendation: Substances I, II, V, VI, VII are included in item 18 of Schedule IV and are controlled substances. Substances III, IV, VIII and IX are not included in the schedules to the CDSA and are not controlled substances.

September 25, 2008