Drug Status Report

Drug: Naloxonazine dihydrochloride hydrate

Drug Name Status: Naloxonazine dihydrochloride hydrate is the common name

Chemical Name: Morphinan-6-one, 4,5-epoxy-3,15-dihydroxy-17-(2-propenyl)-, ((5a)-4,5-epoxy-3,15-dihydroxy-17-(2-propenyl)morphinan-6-ylidene)hydrazone, (5a)-

Chemical structure:

Molecular Formula: C_{39}H_{42}N_{4}O_{6}

Pharmacological class / Application: opioid receptor antagonist

International status:

US: Naloxonazine is not listed in the Schedules to the CSA and is not mentioned on the DEA website. However the definition of narcotic drug in the CSA “(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation” may include naloxonazine.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Naloxonazine is an irreversible antagonist of the opiate receptor and is
derived from naloxazone, a synthetic derivative of naloxone\(^1\). Although naloxone and its hydrochloride salt are both excluded from item 1 of Schedule I of the CDSA under the “but not including” part of this item, naloxazone is a derivative of naloxone and therefore considered to fall under the heading for item 1 of Schedule I: Opium poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including. Accordingly, naloxonazine is also included under item 1 of Schedule 1 to the CDSA.

Recommendation: Naloxonazine dihydrochloride hydrate is included in item 1 of Schedule I to the CDSA and is a controlled substance.

March 8\(^{th}\), 2010.