Health Canada Santé Canada

STATUS DECISION OF CONTROLLED AND NON-CONTROLLED SUBSTANCE(S)

Substance: Veliparib

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled ☐
Not Controlled ✓

under the schedules of the *Controlled Drugs and Substances Act* (CDSA) for the following reason(s):

- The substance does not contain the root structure of the benzimidazoles and therefore cannot be included under item 13 of Schedule I to the CDSA.

Prepared by: _____ Date: March 1st, 2012
Evelyn C Soo

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

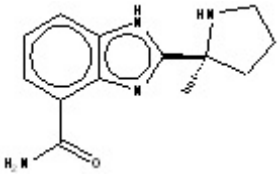
Drug: Veliparib

Drug Name Status: Veliparib is the proper (INN) name.

Chemical Name: 2-((2R)-2-methyl-2-pyrrolidinyl)-1H-benzimidazole-4-carboxamide

Other Names: ABT-888; ABT-888

Chemical structure:



Molecular Formula: $C_{13}H_{16}N_4O$

Pharmacological class / Application: Poly(ADP-ribose) polymerase inhibitor

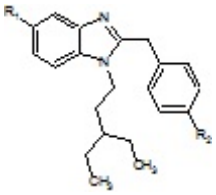
CAS-RN: 209414-16-4

International status:

US: Veliparib is not listed specifically in the Schedules to the US *Controlled Substances Act* and is not mentioned anywhere on the DEA website.

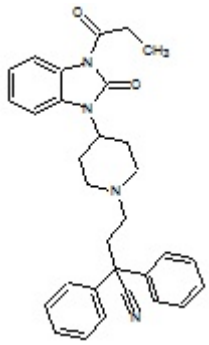
United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control.

Canadian Status: Veliparib is reportedly used for the treatment of cancer[1] and is not listed in the CDSA. The substance is a benzimidazole but does not contain the structural elements of those listed under item 13 in Schedule I to the CDSA (see below) below:



Clonitazene R_1=NO_2, R_2=Cl
Etonitazene R_1=NO_2, R_2=OC_2H_5

[1]Penning, TD et al. (2009) Discovery of the poly(ADP-ribose) polymerase (PARP) inhibitor 2-((R)-2-methylpyrrolidin-2yl)-1H-benzimidazole-4-carboxamide (ABT-888) for the treatment of cancer, J Med Chem. **52**:514-523.



Bezitramide

The status of a number of benzimidazoles have previously been reviewed and it was deemed that those which do not core the root structure of the above-mentioned benzimidazoles are not considered captured under item 13 “Benzimidazoles, their salts, derivatives and salts of derivatives including” of Schedule I to the CDSA. Since veliparib does not contain the root structure of the benzimidazoles in schedule I, it cannot be included in the CDSA.

Recommendation: Veliparib is not included in the schedules to the CDSA and is not a controlled substance.

Date: March 1st, 2012.