National Agency for the Safety of Medicines and Health Products

FRENCH REPUBLIC

Decision of
amending the list of substances classified as narcotic drugs

The Director-General of the French National Agency for the Safety of Medicinal and Health Products (Agence nationale de sécurité du médicament et des produits de santé),

Having regard to the Public Health Code, in particular Articles L. 5132-1, L. 5132-7, L. 5132-8, L. 5432-1, R. 5132-27 et seq.;

Having regard to the Criminal Code, in particular Articles 222-34 to 222-43 thereof;

Having regard to the amended Order of 22 February 1990 establishing the list of substances classified as narcotic drugs;

Having regard to the opinion of the Standing Scientific Committee on Psychotropic Substances, Narcotic Drugs and Addiction of 2 April 2024;

Whereas the abovementioned amended Order classifies as narcotic drugs, in Annex I thereto, the following substances belonging to the chemical family 'nitazenes' pursuant to decisions of the United Nations Commission on Narcotic Drugs: *clonitazene, etodesnitazene (etazene), etonitazene, isotonitazene, metonitazene, N-pyrrolidino-etonitazene (etonitazepyne), protonitazene;*

Considering the pharmacological effects of certain substances of the chemical family 2-[(2-benzyl)-benzimidazole-1-yl] ethanamine, also known as nitazenes, the serious intoxications reported after consumption of these substances which could require emergency medical care, the high risk of accidental, potentially fatal overdose and the risk of abuse and addiction;

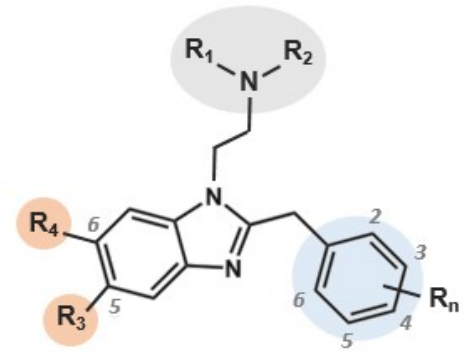
Whereas, in view of their effects, those substances should be classified without delay in the interests of public health,

Hereby decides

Article 1: The list referred to in Article L. 5132-7 of the Public Health Code shall be drawn up in accordance with the annexes to the aforementioned Order of 22 February 1990, subject to the amendments introduced by this Decision.

Article 2: The following words are added to Annex IV to the Order of 22 February 1990 establishing the list of substances classified as narcotic drugs and in addition to the seven substances listed in Annex I to that Order:

Any substance derived from the chemical structure 2-[(2-benzyl)-benzimidazole-1-yl] ethanamine:



- with or without ethanamine nitrogen substituted by the following groups (R_1 and/or R_2): alkyl or alkenyl (up to three carbons), or with ethanamine nitrogen forming part of a cyclic structure;

- with or without the benzimidazole core substituted in position 5 and/or 6 by the following groups (R_3 and/or R_4): alkyl, acetyl, nitro, amino, trifluoromethyl, methoxy, trifluoromethoxy, cyano and halide such as fluorine, chlorine, bromine or iodine;

- with or without the phenyl core of the benzyl system substituted in positions 2 to 6 by the following groups (Rn):

- alkyl, haloalkyl, alcoxy, haloalkoxy, each up to six carbons;
- trifluoromethoxy, acetoxy, trifluoromethyl, hydroxy, cyano and halide such as fluorine, chlorine, bromine or iodine;
- alkylsulfonyl, thioalkyl, each up to five carbons;
- with benzylic carbon that can be substituted by one or two methyl groups or benzylic carbon substituted by a nitrogen, oxygen or sulphur atom;

- with or without the substitution of the phenyl core of the benzyl system in position 3 and/or 4 by an alcoxy group (up to four carbons), whether or not to form a cyclic structure.

These include: *5-amino-isotonitazene, dimetonitazene, ethyleneoxynitazene (tetrahydrofuranitazene), ethylthionitazene, etodesnitazepyne, etodesnitazepipne, etomethazene, flunitazene, isotodesnitazene, menitazene, methylthionitazene, metodesnitazene (metazene), metomethazene, N-desethyl-etonitazene (noretonitazene), N-desethyl-isotonitazene (norisotonitazene), N-desethyl-protonitazene (norprotonitazene), nitazene, N-piperidino-etonitazene (etonitazepipne), N-piperidino-protonitazene (protonitazepipne), N-pyrrolidino-metonitazene (metonitazepyne), N-pyrrolidino-protonitazene (protonitazepyne), protodesnitazene.*

Article 3: This Decision shall be published on the website of the National Agency for the Safety of Medicines and Health Products.

Done on