

Know-X Rapid Alert

Administrative information

Type of reporting entity: Health

Name of the reporting entity: Swissmedic

Reporting country: Switzerland

Reporting date: 22/01/2020

Main contact:

Phone:

Email:

Laboratory / Authority case number: 20191204_01

Other contact:

Phone:

Email:

Sample provider: Patient/Private person

Date of seizure: 04/11/2019

Sample origin: Internet confidential, can be provided upon request

Product description

Product type: Unclear Slimming Tea

Medical device group:

Medical device class:

Notified Body name and address for MD:

MD registered with competent authority:

Product name labelled: Vy&Tea (HAVYCO)

Dosage form: Granules Teabag

Active ingredient labelled: 100 % herbal

Strength:

Unit of measurement:

Therapeutic class labelled: Slimming agents

Packaging type: Bags Bag

Primary/Secondary: primary

Batch number:

Expiry date: 08/2020

Unique identifier (A list can be attached at the end):

Quantity (seized or received) and/or pack size: 15 teabags in a box

Language labelling: Other, English, German Vietnamese

Manufacturer/Marketing authorisation holder: Manufacturer

Name: Unknown, made in vietnam

Distribution path: Internet (give URL adress) one Swiss website which has been closed, and many still active international sellers

Legal status in the reporting country (from a regulatory perspective): Unlicensed

Product assessment

Analysed: Yes

Active ingredient identified: sibutramine

Strength: 20

Unit of measurement: mg/unit

Analytical information:

Mass Information

Other analytical parameters:

Details for mass information:

Outcome

Analytical conclusion: Undeclared API different samples had different composition (see comments below)

Criminal phenomenon: Falsified

Follow-up / Actions

Involved authorities: Enforcement team, Local authority Cantonal authorities

Public health risk assessment: Persons were harmed Swiss person experienced side effects after treatment

Risk communication: Rapid alert WGEO, Warning on website

Withdrawal / Recall information: No recall

Additional information / comments

Results between 16.8 mg and 21.6 mg of sibutramine / bag,

one sample contained additional Phenolphthalein.

Photos

