Issue: Classification of an oral spray

Description:

The product is a transparent liquid available in 30 ml spray bottle and contains 1.2 mg of melatonin as the active substance, glycerine, mint flavour and water.

The product is used for the short-term treatment of primary insomnia (persistent difficulty in getting to sleep or staying asleep, or poor quality of sleep) in patients aged 55 years and older. "Primary" means that the insomnia does not have any identified cause, including any medical, mental or environmental cause.

Headings under consideration: 22.02 & 30.04

Heading 22.02: "Waters, including mineral waters and aerated waters, containing added sugar or other sweetening matter or flavoured, and other non-alcoholic beverages, not including fruit, nut or vegetable juices of heading 20.09".

Heading 30.04: "Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale".

Basis of ruling:

It should be pointed out that Note 1 (e) to Chapter 22 stipulates that Chapter 22 does not cover "*Medicaments of heading 30.03 or 30.04*".

In addition, Note 1 (a) to Chapter 30 excludes "*foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters*)" from Chapter 30.

The product is used on its own for the short-term treatment of primary insomnia and contains 1.2 mg per bottle of melatonin as the active substance. However, the product is not used as a sleeping pill.
Furthermore, because melatonin has most often been used by adults in doses up to 8 mg by mouth daily for up to 6 months, 1.2 mg per bottle is not considered to be a sufficient quantity.

It was decided by the HS Committee of WCO at its 21st Session (March 1998) that "the scope of headings 30.03 and 30.04 should be limited to products used in medicine which contain, per dose, a sufficient quantity of an active substance with a curative or prophylactic effect against a particular ailment or disease, except certain special cases (e.g anesthetics, nutritional preparations for intravenous administration). The determination of active substances could be based on details made available at the time of importation or by laboratory analysis".

Conclusion:

Therefore, the product is considered as a beverage and not as a product put up for a particular ailment or disease and containing a sufficient quantity of an active substance with a curative or prophylactic effect against that particular ailment or disease.
Hence, heading 30.04 is ruled out and classification of the product is considered in **heading 22.02, subheading 2202.99,** by application of GIRs 1, (Note 1 (a) to Chapter 30) and 6.

(Source: WCO members' website - Doc Ref: L 10499)