

PHARMACOVIGILANCE OF SLEEP AIDS, AN ITALIAN EXPERIENCE

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Introduction: There is increasing interest in exploring the use of social media data for pharmacovigilance, but questions remain regarding how to best leverage this data source. Such an issue could be of special interest for what concern food supplement for which a direct advertising to consumer exists, thus introducing variables in the reporting patterns.

Materials and methods: NovaNight (NN) is a recently marketed food supplement containing Melatonin, vitamin B6 and three different herbal extracts which are well known to ameliorate sleep, namely California poppy (*Eschscholzia californica* Cham.), Lemon balm (*Melissa officinalis* L.) and passiflora (*Passiflora incarnata*). This newly marketed product has been largely supported by online advertising on Facebook and other major digital platforms, thus giving the chance to consumer to directly comment on their experience with this product. As part of the pharmacovigilance activity on SANOFI food supplement, all these comments were screened to detect adverse reaction. Comments mentioning the food supplement not reaching the desired effect (i.e. reducing sleep latency or improving quality of sleep) were classified as "lack of efficacy" and included in this analysis.

Results: In the period between the launch of the product (Sept 2018) and February 2019, a total of 81 lack of efficacy complains were detected on the Facebook out of 240.000 units sold (0.34 cases/1,000 units sold).

Discussion and conclusion: Here we have described the pattern of reporting during the first months of selling of a newly marketed food supplement in the Italian market. Such a screening offers an intriguing opportunity to evaluate which factors are associated with the reporting patterns of a newly developed product and provide insights for the evaluation of pharmacovigilance signals for food supplements.