



## Letter to the Editor

## Interpreting data on alpha-lipoic acid safety considering the number of subjects exposed



Dear Editor,

We have read with attention and interest the recent paper of Raschi et al. [1], analysing spontaneous reports of suspected adverse reactions to alpha-lipoic acid included in the Italian Phyto-vigilance System (IPS). The conclusion of the authors suggests the need for a strong attention to the use of alpha-lipoic acid because of an unpredictable risk of serious side effects. However, we would like to stress some concerns about these data interpretation. In the paper of Raschi et al. [1] the reports regard different dietary supplements (with different production quality and associated with different components), different kind of patients (often assuming other drugs at the same time) and very rarely with a reported treatment rechallenge. During 18 years, the IPS registered 212 suspected adverse events in 116 subjects. In Italy, in the same period, a conservative estimate from sell-out databases (limited to the pharmacy distribution, excluding selling via web or large distribution) suggests that around 4.000.000 boxes of dietary supplements containing alpha-lipoic acid were sold each year. Considering that a part of boxes contains 20 tablets and also assuming that all were consumed for a whole year by single subjects, we should have an expected rate of people experiencing suspected adverse events of 0.0029%, independently from the strength of association and of severity. This is in line with what reported in the setting of randomized clinical trials, given the high safety profile of alpha-lipoic acid reported in large meta-analyses [2,3]. In conclusion, we agree that a more rigid regulation is desired on dietary supplement production and that frail subjects should be monitored by medical doctors, but that warning should be cautious for a molecule that is demonstrating positive effects in ameliorating the perceived quality of life of patients affected by a number of disturbing diseases [4].

## References

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