



# The Italian paradox of flavonoid use for hemorrhoids

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Dear Sir,

Flavonoids are commonly used in Europe and Asia to treat acutely inflamed and bleeding hemorrhoids, but not in North America, where flavonoids have not been approved by the US Food and Drug Administration (FDA) for the treatment of hemorrhoids.

In Italy, we commonly prescribe flavonoids for the treatment of hemorrhoidal disease. Several papers on this topic come from our country, as shown in the most recent Cochrane review [1], where 8 out of 24 cited articles are Italian series. Moreover, the recent guidelines published by the Italian Society of Colorectal Surgery (SICCR) in 2020 [2], conclude that phlebotonics has a statistically significant effect on symptoms caused by hemorrhoids and recurrence of hemorrhoidal disease.

In Italy there are many flavonoid preparations which are sold both as drugs and as supplements. Usually, as clinicians, we prefer to prescribe drugs to our patients, because of more precise control both during production and marketing.

In Italy to market a new drug the producer has to test its safety, efficacy and quality, while to market a supplement only safety and quality are tested, not efficacy.

Moreover, the strictness of the controls are very different between drugs and supplements. Drugs are subjected to the analysis of pre-marketing data by a specialized commission (Agenzia Italiana del Farmaco—AIFA) and also to periodic tests, after marketing, on the concentrations of active particles. Furthermore, in the post-marketing phase, the drugs are subjected to the collection and reporting of side effects.

However, to commercialize flavonoid based supplements only a notification letter is required by the AIFA before marketing. In Italy hemorrhoidal disease is not reported as

an indication for treatment with any flavonoid-based drug (AIFA schedule), thus every prescription made by a general medical practitioner or proctologist is “off label”, leading to medical legal implications and requiring specific written informed consent to be obtained from each patient (Law 94/1998).

On the other hand, in the package leaflets for several flavonoid supplements the list of indications for use includes hemorrhoidal disease. So here is the Italian paradox: proctologists would like (and prefer) to prescribe flavonoid-based drugs instead of supplements because they are clinically safer and controlled. Unfortunately they are induced by AIFA schedule deficiencies and by marketing to prescribe flavonoid supplements to avoid legal issues.

## Compliance with ethical standards

**Conflict of interest** The author declares that he has no conflict of interest.

## References

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