



Tell HPB...

SAMet is not a drug!



Canadians from all walks of life

have made it clear... that they are taking charge of their health.

They want **freedom of choice** in making health decisions. And, they want enhanced access... to a full range of natural health products”.

-HPB Web site



SAMet (s-adenosylmethionine) was first introduced to Canada by Advanced Orthomolecular Research, the flagship label of Holistic International, in October of 1998. At the time, it was an unknown, and thus demand for the product was not impressive, but AOR continued to quietly sell our stable, reliable formulation, pleased to be helping so many of our customers return safely and naturally to health.

All this changed by mid 1999, as North Americans discovered what health-conscious Europeans have known for twenty years: that SAMet is a remarkably safe and amazingly effective **antidepressant**, as well as providing support for **osteoarthritis**, **liver function**, **fibromyalgia**, and perhaps the **aging process** itself. We were happy with the increased sales, but at the same time, we were saddened by the many poor-quality imitation products which began to flood the market: products mislabeled as to content (indicating the amount of *total complex* rather than *active SAMet ion*); products not stably enteric-coated or packaged; products using poor-quality raw materials; and some products containing *no SAMet at all*. So when we learned that a major Canadian health magazine was running a feature on SAMet, AOR felt the time was right to place an ad outlining the quality issues

differentiating our product from the many misleadingly-labeled or outright fraudulent products.

How ironic, then, that just one day after we had submitted this ad, we received notice that *Health Protection Branch (HPB) was banning SAMet* for sale in Canada. We – and other SAMet manufacturers and distributors across Canada – were notified that SAMet had been placed in **Section 2.1** of the Therapeutic Products Compliance Guide. This section declares a substance a *drug*, even in the absence of claims, and means that, before the product can be sold again, each manufacturer must go through the sort of approval process normally required for synthetic drug pharmaceuticals, rather than that applied to vitamins. Sometimes called the “**black hole**,” this status essentially ensures that a substance will never come to market: on the one hand, it cannot be freely sold as a nutritional supplement, like calcium supplements; on the other hand, because it cannot be patented, even a pharmaceutical giant would not invest the enormous amount of money required to undergo the process required to get approval, since their capital would go to a product which they could not exclusively control. For reference, this is the same status that has kept melatonin out for reach of Canadians except by mail order or black



A Cut above The rest

market for almost a decade now. While we are complying with this new legislation, we are outraged by it, as have been many of our customers. Since the ban, we have received many calls, ranging from the furious to the despondent, from retailers

the substance is marketed in several European countries for the treatment of depression, liver disorders, and osteoarthritis ...

and individuals telling us how much SAMet had helped them, their clients, or their loved ones, and begging us to sell them just a few more bottles. And, bitterly, it is just this help – as reported not just by our customers, but by dozens of double-blind, placebo-controlled trials published in peer-reviewed medical journals – which HPB insists makes SAMet a Section 2.1 drug! To quote from one letter (99-038629) we were sent: “This determination is supported by the fact that the substance is marketed in several European countries for the treatment of depression, liver disorders, and osteoarthritis ... Information and promotions from the internet advocate **drug** [their emphasis!] uses for SAME, eg, ‘SAME is critical in the maintenance of cartilage and in the manufacture of important brain compounds such as neurotransmitters.’ Of course, to all but the jaundiced eye of a hostile bureaucracy, these are *not* “**drug** uses,” any more than the statement that “vitamin C is critical in the maintenance of healthy bones and gums and the manufacture of important structural compounds such as collagen” advocates “**drug** uses.” Rather, these claims describe the *normal physiological function of these biologically essential substances*. HPB recognizes, and allows, the latter claim on vitamin C bottles; how do the former claims, placed on the *internet* or in *magazine articles*, constitute “**drug** uses”?

We are sympathetic to those who will now be denied access to this powerful, versatile, highly safe compound, and outraged at the lack of consultation with the industry, or respect for the democratic process, evidenced by this decision. We know that

SAMet users feel the same way, and expect that many non-users will be angered by the continued assault on their health freedom, even though the decision does not affect them personally. Concerned citizens may wish to contact the Minister responsible for oversight of HPB. Hopefully, with the imminent activation of the new **Office of Natural Health Products**, public pressure will allow the ONHP to wrest SAMet away from Section 2.1 drug status, and place it where it clearly belongs: as a natural health product, in the hands of health-conscious Canadians.

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