Letter to the Editor

Counterstatement to the Article «Bioavailability and Chemical/ Functional Aspects of Synthetic MK-7 vs Fermentation-Derived MK-7 in Randomised Controlled Trials» by Mona Møller et al.

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We at NattoPharma applaud the authors of this new paper *"Bioavailability and Chemical/Functional Aspects of Synthetic MK-7 vs Fermentation-Derived MK-7 in Randomised Controlled Trials"*, and your journal for publishing an article to further increase the understanding and importance of Vitamin K2 as *Menaquinone-7 (MK-7)*. Nattopharma has been at the forefront of sponsoring and publishing Vitamin K2 research for the past 10 years and we are encouraged to see efforts to build the body of knowledge.

However, we have a considerable issue with the conclusion the authors of the article are attempting to make, namely drawing a correlation to our ingredient, *MenaQ7®* vitamin K2, by errantly stating that the material used comparatively in this paper is identical to our material.

The authors have cited our work in several important, ground breaking studies referenced in this article that specifically utilize NattoPharma's branded Vitamin K2 as *MK-7, MenaQ7*, including:

1. Reference #15: Knapen, M.H., Drummen, N.E., Smit, E., Vermeer, C. and Theuwissen, E. (2013) Three-year low-dose menaquinone-7 supplementation helps decrease bone loss in healthy postmenopausal women. Osteoporosis. Int. 24, 2499 – 2507.
2. Reference #28: Knapen, M.H.J., Vermeer, C., Braam L.A.J.L.M. and Theuwissen, E. (2014) Pharmacokinetics of menaquinone-7 (vitamin K2) in healthy volunteers. J. Clin. Trials 4, 160.
3. Reference #39: Knapen, M.H., Braam, L.A., Drummen, N.E., Bekers, O., Hoeks, A.P. and Vermeer, C. (2015) Menaquinone-7 supplementation improves arterial stiffness in healthy postmenopausal women: double-blind randomised clinical trial. Thromb. Haemost. 113, 1135 – 1144.

The Materials and Methods sections of these studies clearly state that Vitamin K2 as *MK-7* was "MenaQ7, NattoPharma ASA, Hovik, Norway." However, this is not specified in either the article itself or the reference section. Further, the last sentences of the Limitations and Strengths section clearly tries to connect NattoPharma's studies with the material being discussed in this article, which is from Kappa BioScience, manufactured by J-Oil Mills. We believe this portion should be shortened:

> "An important strength of our studies is the use of fermentation-derived MK-7 produced by J-Oil Mills as the active ingredient in the control product, ~~because this was used in recently published clinical studies on the effects of MK-7 [9, 15, 39, 40]. This strengthens our ability to compare our present findings with published findings on MK-7.~~"

The *only reason* this statement is included is to attempt to link the blood study being discussed to NattoPharma's studies, importantly in (15) *Osteoporosis International* 2013, and (39) *Thrombosis and Haemostasis* 2015.

NattoPharma has been at the forefront of Vitamin K2 research and development since the company's inception. We have partnered with leading research institutions and sponsored most of the core studies that have contributed to our current understanding of Vitamin K2 as MK-7, and that research has shaped our branded material, *MenaQ7*.

To that end, we feel compelled to correct the inaccurate statements made by the author and state plainly that we disagree that this is a valid representation of this study's connection to the groundbreaking work that has come before. It is impossible that Kappa can know or have used the same formulation as our *MenaQ7*. Further, it is highly inappropriate to attempt to use a statement from another company *not involved* in our studies, to attest to the actual material preparation used in the trial. Therefore, we believe Reference #40 should be omitted from the article.

~~Reference #40: J-Oil Mills. Fermentation-derived MK-7 produced by J-Oil Mills was used in the studies in references 15 and 39. Personal communication, 25 June 2015.~~

In closing, NattoPharma asserts that the authors deliberately omitted an important fact that the capsules used in the 3-year clinical trials (refs 15 and 39) contained MK-7 as *MenaQ7*, and mislead readers to believe that a different company provided their K2 as the source material for that study (ref 40). This represents an unethical behavior that the authors should have agreed to correct for the betterment of the journal's readers.

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