Seminar:

Bioactive compounds in food

“Documentation of effects including analyses and methods for clinical trials”

Gunnar Kvistgaard

Regulatory affairs &
Product development

Why the double title?
Double the work; half the trouble

Industrial challenges in documenting effects of bioactive food compounds in a health claim

Health claim types

A health claim: A claim that states a relationship between a food category, a food or one of its constituents and health

Or

A reduction of disease risk claim: I.e. Any health claim that states that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

Article 13 claims

13.1 based on generally accepted scientific evidence
(now closed)

13.4 the above + additional information seen as:
Generally accepted scientific evidence (SME option?)

13.5 as 13.1 but including proprietary data giving a possible 5 years protection period

Article 14 claims

- Article 14,1
  Claims requiring a high degree of documentation and open for all to use

- or 14.5
  Claims requiring a high degree of documentation including proprietary data giving a possible 5 years protection period

Challenges

- Who is supposed to benefit from my documentation?
- The need of general claims for all operators
- The wish to promote your own product
- The cost related to already made studies
- The cost related to additional studies and how to “reclaim” your investment.

The studies to include:

- Quality/strength of study (the golden standard)
- Number of studies needed proving your claim
- Relevance of studies; i.e. How specific documentation is needed
- Animal studies

The Golden standard

Golden standard quality

Randomised, double blinded, placebo controlled

human studies

Preferably peer reviewed, published in high

esteemed papers .

Where can such studies be made?

Hospitals Who are hospitalised? Patients

Quality and strength of the study
The golden standard

- High quality studies which are:
- Peer-reviewed
- Randomised
- Double blinded
- Placebo controlled

- Are not acceptable as they are not carried out on healthy individuals.
- The Challenge of the ”Golden standard”

The catch and the hurdle:

- Documentation is only acceptable if it is made on healthy human individuals in the target group

The application

- Decide the type of health claim you want
- Decide on the preferred ”clinical” wording of the claim.
- Thoroughly prepare the wording desired. Must be well understood by the average consumer.
- Do not worry about the quality of studies in relation to the claim type chosen.
- Do worry about the quality of your studies.

- Requirements are the same no matter the claim type (The Golden standard).
- Then start praying!

The Challenge of the ”Golden standard”

- New high quality studies made on healthy individuals:

- Who are in the target user group
- Where bio-markers are identifiable
- Where the outcome is strongly convincing

- OR?

Another solution

- Using the thousands of studies made on ”patients” as documentation on healthy people in the target group.

  ”How to”?

- ”Tie” studies together with a quality study using identified values from bio-markers as defiend end-points in studies made with patients and a control-group of healthy people from the target group and ”link the two groups together.

The Comparison

Food vs Pharma

Traditional herbal medicinal products, Directive 2001/83/EC

- (a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and

  designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

- (b) they are exclusively for administration in accordance with a specified strength and posology;

- (c) they are an oral, external and/or inhalation preparation;

- (d) the period of traditional use as laid down in Article 16c(1)(c) has elapsed;

- (e) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

Thank you