Seminar:

Bioactive compounds in food

"Documentation of effects including analyses and methods for clinical trials"



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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

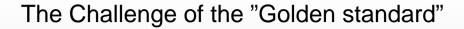
- High quality studies which are:
- Peer-reviewed
- Randomised
- Double blinded
- Placebo controlled
- Are not acceptable as they are not carried out on healthy individuals.
- The Challenge of the "Golden standard"

The catch and the hurdle:

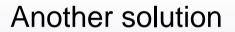
 Documentation is only acceptable if it is made on healthy human individuals in the target group

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.
- <u>Do not</u> 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!



- 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?



• 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



