

Make your claims regain health!

How to continue to communicate on the efficacy of products in health nutrition?

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Beginning 2012, with the publication of the regulation of generic claims, the transitional period during which manufacturers could still communicate almost as they wish will come to an end, and the rejected claims can't be used (joint, diuretic etc ...). We'll get into the new model of validation a priori by the EFSA and the European Commission of health claims submitted through a claim file.

REGULATION 1924/2006, A REVOLUTION FOR THE COMMUNICATION IN HEALTH NUTRITION

Regulation 1924/2006 has completely upset the rules of the game for communication on the products. Yesterday, the positioning and the benefit of the product were recovered by promises extremely striking and attractive to the consumer, based on scientific evidence more or less solid or traditional use. Now, the health claim must be substantiated by scientific evidence and validated prior to its use by scientific and regulatory authorities, EFSA (European Food Safety Authority) and the European Commission.

While the claims contained in the positive list of approved generic claims can be used by manufacturers, with the sole condition of respecting the defined conditions of use, any generic claim not listed on this list will be prohibited. These generic claims will claim on a normal function by an ingredient or product. But simple and low cost use of generic claims could quickly lead to a unified market, product standardization, of both compositions and claims.

As opposed to generic claims, specific claims allow manufacturers to differentiate their product from the competitors with a claim which is unique, original and proper to the product. But this way of communication, specific to a product, requires experience and expertise, and undeniably significant costs in terms of time and money to properly justify the claimed efficacy, by specific proprietary clinical evidence presented to EFSA in an application for authorization of health claim.

THE HEALTH CLAIM FILE, TO KNOW THE RULES TO CONVINCE EFSA

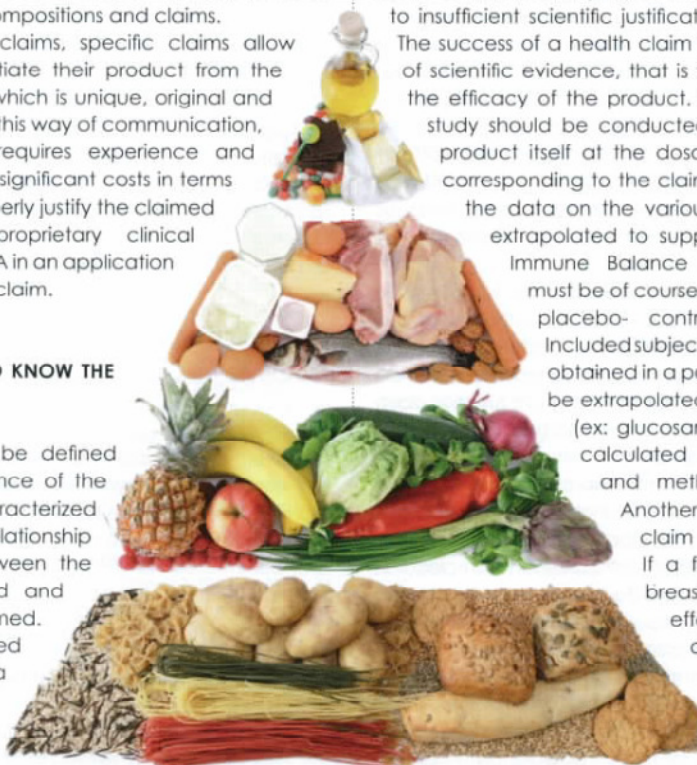
A health claim file can be defined as all the scientific evidence of the efficacy of a well characterized food/ ingredient. A relationship must be established between the consumption of this food and the health benefits claimed. Characterization is justified by its specifications, data of stability, variability, bioavailability etc... The efficacy is justified by at

least one clinical study on the product itself and must provide health benefits.

While some files, which were among the earliest submitted and assessed by EFSA, received positive opinions, a majority of assessed files/claims are rejected. In the first batch of generic claims published in October 2009 over 523 claims assessed in 94 opinions, 63% were negative. In February 2010, for the second batch of 416 claims assessed in 31 opinions, 98% were negative! This negative trend was maintained at 80% with the third batch delivered in October 2010 over 808 claims assessed in 75 opinions. Recently, in April, for the 4th batch of 442 claims assessed in 63 opinions, 83% were negative. Regarding the specific claims, the level of success is low but it is also increasing steadily, going from only 17% positive opinion in November 2010 to 25% in April 2011. Note that these accepted claims mainly relate to nutrients, vitamins, minerals, phytosterols, omega 3, tomato concentrate and xylitol, but no plant extract or unexpected ingredient in providing innovation to market. Why? What are the reasons that may explain such a low success rate?

THE REASONS OF SUCH A LOW SUCCESS RATE

Regarding the first criteria for evaluating a health claim file, characterization, experience shows that only a few of files had an insufficient characterization of the ingredient. It appears however that the majority of negative opinions are related to insufficient scientific justification for the claimed effect. The success of a health claim file depends on the quality of scientific evidence, that is to say the studies, justifying the efficacy of the product. In any case, a convincing study should be conducted on the ingredient or the product itself at the dosage and conditions of use corresponding to the claim applied for. It seems that the data on the various components cannot be extrapolated to support the product itself (ex: Immune Balance Drink). The methodology must be of course: randomized, double-blind, placebo- controlled (golden standard). Included subjects must be healthy, the results obtained in a population of patient can not be extrapolated to the general population (ex: glucosamine), and the sample size calculated a priori. Finally, markers and methods must be validated. Another key point in evaluating a claim is the health relationship. If a few health relationships as breast enhancement, diuretic effect or antioxidant effect are not accepted, the vast majority of applications and health relationships have been approved by EFSA.



Besides these technical considerations of sufficient characterization of the ingredient, the health relationship and scientific evidence justifying the claimed effect, we nevertheless question the fact that vitamins and minerals are mainly positively evaluated relative to plants or other ingredients that are regularly rejected. The recent positive opinion obtained by thiamine in Article 14 on children health for the application « Thiamin and maintenance of normal neurological development and function » is an example. Why such discrimination between evaluation reserved for vitamins/ minerals, whose benefit is established on the fact that the deficiency is deleterious, and one made with other ingredients, whose benefit should be established on the fact that consumption provides real statistically significant effect, when all these ingredients should be evaluated in the same manner as the application of Regulation 1924/2006 should be strictly the same for all actives subject to an application for claim. If we can shed light and provide a better understanding of the lacks of the files and if it helps to accept the many negative opinions, this does not solve the problem. How to continue to communicate on the health benefits of products?

DIFFERENT STRATEGIES TO COMMUNICATE

The simplest, quickest and cheapest solution, which, on the other hand, is less original, and does not allow distinguishing one product from another in a competitive market, is the use of the so-called generic claims. With the only condition to use the correct ingredient (that is to say a vitamin or mineral because of the very small chances of success for other ingredients) at the right dose, any industrial may use a claim defined. As mentioned above, this could quickly lead to a homogenization of the market, product standardization in terms of both compositions and claims. However, to "save" the product and continue to position them for the consumer with claims, in a first time we strongly encourage the use of this quick and easy solution.

The solution to use a proprietary and original claim is to obtain approval by a procedure in article 13.5 or 14. Even if this process is long (from 12 months to much more between the constitution of the file and the scientific opinion from EFSA) and very expensive since it requires at least one good clinical study, such a claim can differentiate a product from its competitors. Note that once a claim receives a positive opinion it will be usable throughout the European Union that is to say in the 27 Member States. This is the promise of a powerful business development, also internationally, our European system becoming the reference, which we have recently satisfied again through an exchange with the FDA. Another extremely important point is data protection for five years for health claim files under article 13.5.

While this new regulation restricts the communication to the public, what about the one made with health professionals? The regulation is ambiguous on this concept which would leave an additional opportunity to communicate on the benefits and efficacy of products.

Out of the Regulation 1924/2006 and the application for authorization of a health claim, there are not a lot of alternatives to communicate on the health