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Europe's Botanicals Deadlock 'Unlawful,' Claims Industry Lawyer

by David Ridley

The European Commission's "obvious passivity" with regards to the long-standing botanical health claims deadlock is "illegal and violates the provisions of the EU Health Claims Regulation," argues the German Pharmaceutical Industry Association, on the basis of a legal opinion provided by former constitutional judge Udo Di Fabio.

The European Commission is acting unlawfully by allowing the now 12-year deadlock concerning the evaluation of European Union herbal food and food supplement botanical health claims to drag on, a recently published legal opinion claims.

The opinion, provided by former constitutional judge Udo Di Fabio, "shows that the Commission's obvious passivity is illegal and violates the provisions of the EU Health Claims Regulation," commented Kai Joachimsen, general manager of the German Pharmaceutical Industry Association, which commissioned the opinion alongside the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE).

The situation – which involves more than 2,000 botanical heath claims being placed "on hold" while the Commission decides what to do, meaning that they can continue to be used despite being deemed to have unsatisfactory scientific backing – "not only deceives consumers," Joachimsen continued, "but also risks the Commission being jointly responsible for the decline of an entire sub-sector, namely the manufacturers of herbal medicines."

European Industry Divided

In his comments, Joachimsen points to the negative impact that the "on-hold" situation is having on the pharmaceutical side of the consumer health industry, in particular manufacturers of traditional herbal medicines.

"As long as the food manufacturers are practically exempt from the obligation to have the proof of efficacy confirmed by the European Food Safety Authority due to the unlimited application of the transitional provision, they gain a clear advantage over the companies that market the substance as a medicinal product," he added.

German Industry United

The German Medicines Manufacturers' Association, BAH, also supported Di Fabio's opinion, saying that it confirmed the association's own approach to the ongoing botanicals issue.

"BAH has always been advocating an adequate assessment of food supplements including supplements with herbal ingredients," commented BAH's managing director of scientific affairs, Elmar Kroth.

"This includes an evaluation of the claims made and does not question the availability of such products provided they follow the rules laid down in the food supplement directive of the European Union," he continued.

"BAH believes that requirements established in the EU legal system need to be implemented," Kroth added. "Otherwise, European citizens lose confidence in the consistency of the European system."

In a survey commissioned as part of its ongoing reflection, the EC found a significant gap in perspectives between supplement manufacturers classed as "food business operators" and those classed as part of the pharmaceuticals sector.

Food business operators "judged favorably" the current on-hold situation, as it "avoided serious negative implications" for competitiveness, the Commission noted.

Meanwhile, the "vast majority" of pharmaceutical sector consultees indicated that the implementation of the on-hold list of health claims had had a "strong negative impact on their sector," the research found.

When it came to the question of how botanicals claims should be regulated in future, the pharmaceutical industry consultees were in favor of regulating them the same as other food supplement claims – i.e. as EFSA had done when it rejected all botanicals claims.

In particular, pharmaceutical companies said that their competitive position on the market would experience a "strong positive impact" in this scenario, and also that innovation – specifically the launching of new products – would "experience a strong positive impact, and export opportunities may increase," according to the Commission.

"It is not up to the European Commission to ignore rules adopted by the European legislator."

On Hold

Designed to protect consumers from unsubstantiated and unauthorized health-related claims for foods and food supplements, the 2006 European Union Health Claims Regulation (EC 1924/2006) should have been fully implemented by 31 January 2010 at the latest, as stated by Article 13(3) of that regulation.

However, due to concerns raised by several EU member states and industry stakeholders with regard to the different regulatory regimes for health claims in food and food supplements on the one hand, and traditional herbal medicinal products on the other, the EC initiated a period of reflection on the issue of botanicals.

Pending the outcome of its reflection, the Commission asked EFSA, which had by this point rejected a number of botanical claims, to discontinue its scientific assessment of the health claims.

Later, in response to demands made by herbal medicine manufacturer Bionorica and pharmaceutical consultancy firm Diapharm that the EC and EFSA should resume the assessment of botanical health claims, the Commission responded that, "to identify the best course of action needed, the Commission should be allowed the time and context necessary for that purpose."

This response was challenged by the BPI in its latest intervention, pointing out that the EC is "not empowered to simply extend the transitional provisions of a regulation on its own by a mere press release."

"This requires a formal law with the participation of all EU institutions involved in legislation," the association insisted. "The Commission cannot refer to political reflection processes to justify the suspension but must rather fulfill its duties and obligations foreseen in the Health Claims Regulation."

Not A Priority

During its decade long reflection, the EC has periodically updated the European herbals and food supplements industries about its progress, not always with welcome news.

At a meeting of the Association of the European Self-Medication Industry, the AESGP, in 2017, Nathalie Chaze, deputy head of cabinet of then Health and Food Safety Commissioner Vytenis Andriukaitis, told delegates that draft conclusions drawn from this process of consultation would be presented at workshops later that year. (Also see "*German Industry Urges Progress On Botanicals*" - HBW Insight, 19 Mar, 2019.)

These results did not materialize, prompting the BPI to warn German consumers to be wary of unproven health claims for herbal food ingredients in the absence of progress on botanicals regulation.

Then in 2020, the EC got industry pulses racing by suggesting that "traditional use" could be explored as a way to resolve the deadlock, conceding in the process that the objectives of the Nutrition and Health Claims Regulation had not been "fully attained" with regards to botanicals. (Also see "*European Commission Suggests 'Traditional Use' Could Resolve Botanicals Deadlock*" - HBW Insight, 1 Jul, 2020.)

However, excitement was cooled later that year at the BAH's High Level Conference on the Future of Medicines when the EC's Sabine Jülicher admitted that the botanicals issue was "currently not the top priority." (Also see "*Resolving Botanicals Deadlock 'Not A Priority' For European Commission*" - HBW Insight, 2 Dec, 2020.)

"Reflections are ongoing in the background," commented Jülicher, speaking in her capacity as director for Food and Feed Safety Innovation. "But we have no timetable that we could communicate at this point in time."

Interim Solutions

In the absence of a decision from the EC, European industry has been exploring its own solutions.

The European Federation of Associations of Health Product Manufacturers (EHPM) has put forward what it calls a "graded approach" to the assessment of botanical health claims made for food supplements. (Also see "*EU Health Food Industry Proposes Three-Tier Claims System To Break Botanicals Deadlock*" - HBW Insight, 10 Feb, 2021.)

The EHPM is proposing three grades of evidence to support health claims made for foods under the EU Nutrition & Health Claims Regulation:

- A – Scientifically established claims, based on a modified form of the conclusive scientific evidence currently applied by EFSA, with claims taking the form "a contributes to b";
- B – Scientifically well-supported claims, based on a significant body of evidence, with claims taking the form "a can contribute to b";
- C – Traditional-use claims, based on a demonstrated tradition and plausible science, with claims taking the form "a is traditionally used for b".

By contrast to the EC's recent suggestion to use traditional-use evidence in claims assessment – which the EHPM said it supports – the association thinks its more nuanced approach, which also suggests ways that the language of claims can make the different types of evidence more transparent, offers a way to reconcile the evidence requirements of EU Food Law with consumer freedom of choice.

Kitchen Herbs Or Medicines

The Dutch industry association, Neprofarm, has also introduced new measures to tighten up the self-regulation of herbal food supplements in the country, in response to concerns that health claims made for such products are misleading to consumers. (Also see "*As Botanicals Deadlock Holds Back Investment, Dutch Industry Takes The Initiative*" - HBW Insight, 12 Feb, 2021.)

Together with the Inspection Board for the Promotion of Health Products (KAG), Neprofarm critically reviewed and revised the indicative list of health claims language for botanicals so that they are better aligned with those approved and published on the EU Register of nutrition and health claims made on foods.

For example, food supplements targeted at the cardiovascular system are allowed to claim that they "support," have a "beneficial effect" or make a "positive contribution" to the normal functioning of the heart, but not that they can "improve the functioning of" the heart or even prevent cardiovascular diseases.

Commenting on the EC's "traditional use" proposal, Neprofarm's director Bernard Mauritz said, "Either there is the use of herbs in the kitchen or the use of herbs for medicinal purposes. For the latter, we already have traditional herbal medicinal products. It doesn't solve the problem for health claims."

On the EHPM's idea that EFSA could refer to herbal monographs to substantiate botanical food supplements claims, he said: "What's the problem with licensing these products as traditional herbal medicines in the first place?"

"The problem with herbal supplements is that they do not supplement the normal diet," he added. "Rather, they are used as a kind of (preventive) medicinal product without complying with all the requirements for medicinal products. That's the problem."

HBW Insight has approached the European Commission for comment.