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Ginkgo Biloba Extract Is Drug, Not Supplement, Rules German Supreme Court

by David Ridley

Products containing “monograph compliant” ginkgo biloba dry extract as the main active ingredient at recommended doses of 100mg per day should be considered drugs, not dietary supplements, Germany’s federal administrative court has ruled. The decision settles a longstanding dispute between the country’s food regulator and an unnamed company that had applied for registration of such a product.

The highest court in Germany has ruled that products containing “monograph compliant” ginkgo biloba (GbE) dry extract as the main active ingredient at recommended doses of 100mg per day should be considered drugs, not dietary supplements.

The decision issued by Germany’s federal administrative court (BVerwG) settles a longstanding dispute between the country’s food regulator, the Federal Office of Consumer Protection and Food Safety (BVL), and an unnamed company that had applied for registration of such a product.

In 2012, the BVL rejected the company’s application, a decision that the latter challenged unsuccessfully at lower court levels.

In its recent decision, the federal administrative court supported these earlier rulings and the reasons behind them, for example the Lüneburg Higher Administrative Court’s (OGV’s) view that 100mg GbE represented a health risk to consumers.

The OGV had come to the conclusion that there were reasonable doubts about the safety of the GbE products with a dosage of 100mg GbE/day, the BVL explained in its press release on the ruling.

At such doses, products are potentially carcinogenic, increase the risk of bleeding and are the

cause of further non-specific adverse effects on human health, the OGV said.

Adding warning labels to the products would not resolve the issue, the OGV added, as the "risks at issue would exist for all consumers if used as intended" and warnings "would then only serve to raise awareness of the risk than to avoid it."

In response, the plaintiff objected that new clinical trials were needed to establish these claimed health risks, however, this objection was rejected by the latest federal court verdict.

There was "no need for clinical studies on the specific products at issue," the BVerwG explained, as health risks could be derived from studies on medicinal products with a slightly higher GbE dosage.

The BVerwG also rejected another compromise suggested by the plaintiff, that a reference to the exclusive use of the product under medical supervision could be added.

Such restrictions are "intended only for dietary foods for special medical purposes," the BVerwG ruled, and therefore not applicable to this case.

No Surprises

Commenting on the ruling, botanicals expert Mihai Inceu said he is "not surprised" as GbE's pharmacological properties have been widely recognized.

In the European Union, for example, GbE products can be marketed as traditional herbal medicines for the treatment of mild dementia, noted Inceu, who is a senior regulatory affairs officer at UK consultancy firm JensonR+ Limited.

In 2015, the European Medicines Agency's Committee on Herbal Medicinal Products (HMPC) concluded that GbE medicines containing the dry extract "can be used to improve the age-related cognitive impairment (worsening of mental abilities) and quality of life of adults with mild dementia."

The HMPC's conclusions on age-related cognitive impairment and dementia were based on "well-established use," which means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

For minor circulation problems, the HMPC's conclusions were based on "traditional use".

"This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this

way for at least 30 years (including at least 15 years within the EU)," the EMA explains on its website.

Nevertheless, the link between GbE and dementia remains controversial.

As part of its periodic review process, the HMPC issued earlier this year a call for scientific data related to GbE, "so the monograph could be updated," Inceu noted.

Classic Borderline

For Inceu, GbE is a classic case of a "borderline ingredient." In some countries it is marketed as a traditional medicine, in others a food supplement.

In Ireland, for example, Pharma Nord sells its "pharmaceutical grade" GbE product under a traditional herbal license.

Only available through pharmacy, the product contains 100mg GbE per dose and has an approved claim to "support the maintenance of a good blood circulation."

GbE is also available as a dietary supplement in France, Inceu explained, but on the condition that such products must display a warning to "consult a doctor if you are taking anticoagulants at the same time."

"Italy also allows GbE to be marketed with claims for memory and cognitive function," he added.

For manufacturers looking to market GbE products as dietary supplements in the EU, he advised they should keep doses low to avoid legal challenges.

Manufacturers should also check country by country if there are specific rulings that the plant is medicinal regardless of dose or at what doses marketing authorizations are issued, he suggested.