

BVerwG 3 C 40/05 - Urteil vom 14. Dezember 2006

Classification of medicinal products /dietary supplement products; general licence to market; pharmacological action

The plaintiff distributes herbal tablets made according to a Tibetan formula. The product contains a mixture of dried and crushed plants and plant extracts, together with gypsum and camphor. In 1998, the plaintiff applied for a general licence to market the product as a dietary supplement, indicating that it was already being lawfully marketed in Austria. The Federal Office for Consumer Protection (BVL) refused to grant a general licence on grounds that the product is a medicinal and not a food product.

The resultant legal action was disallowed by the Administrative Court, and the appeal dismissed. The Appeal Court based its judgment on the fact that the ingredients of the herbal tablets have a pharmacological action.

The Federal Administrative Court confirms the opinion of the Appeal Court. A product which corresponds to the definition of a medicinal product according to Art. 1 No. 2 of Directive 2001/83/EC is to be treated in Germany according to the medicinal product regulations even if it is marketed lawfully and without objection in another Member State of the European Community. If a product consisting of several active ingredients produces an overall pharmacological action, it is of no consequence for its classification as a medicinal product that the small quantities of the individual active ingredients present mean they produce no such action individually.