

## **Statement of the Ayurveda Umbrella Association Germany (Ayurveda Dachverband Deutschland ADAVED e. V.) on the safety of Ashwagandha**

On 10 September 2024, the German Federal Institute for Risk Assessment (BfR) published a similar communication on the medicinal plant Ashwagandha (bot.: *Withania somnifera*).<sup>1</sup>

The content of the BfR communication is essentially based on a publication on Ashwagandha by Danmarks Tekniske Universitet (DTU) from 15 May 2020,<sup>2</sup> as well as on a BfR publication from 2012 on various medicinal plants.<sup>3</sup>

The recent BfR publications and the DTU report warn of possible risks in relation to thyroid function, the regulation of sex hormones and liver health, among other things, when using Ashwagandha. The BfR report has led to considerable media coverage in Germany, including in the Deutsches Ärzteblatt (German Medical Journal)<sup>4</sup> as well as in other specialised and lay media.

### **The Ayurveda Umbrella Association Germany e. V. (ADAVED) commented as follows:**

Ashwagandha is one of the most frequently used plants in the Ayurvedic tradition and has been used there (as well as in numerous other traditional Asian medical systems) for several millennia for the promotion of health. Only the root and root extracts are used for this purpose - and not, as implied by the references cited in the BfR and DTU publications, other parts of the Ashwagandha plant.<sup>5</sup>

According to the Novel Food Catalogue, Ashwagandha was not classified as a novel food in the European Union, meaning that Ashwagandha was classified as a food or food supplement. The World Health Organisation (WHO) has issued a positive monograph for the root of *Withania somnifera*.<sup>6</sup>

A statement by the European Medicines Agency (EMA) from 2012 also does not address any safety concerns about Ashwagandha.<sup>7</sup>

An expert commission appointed by the German Federal Institute for Drugs and Medical Devices (BfArM) to classify products of the Ayurvedic tradition in 2020 also contains no specific safety concerns or warnings about Ashwagandha.<sup>8</sup>

The publications of the BfR and the DTU mainly refer to basic scientific and preclinical studies on animal models as well as to a few clinical studies of evidence levels IIb-V. The Indian Ministry for Ayurveda (the Ministry of Ayush)<sup>9</sup> has pointed out in a detailed statement by a specially appointed committee of experts that numerous scientific publications on Ashwagandha have not been taken into account in the publications of the BfR and DTU. This has led to an inadequate and scientifically questionable assessment of Ashwagandha.<sup>10</sup> In a summarising statement, AYUSH concludes that Ashwagandha is a safe and effective medicinal plant that is supported by both traditional knowledge and modern scientific research.<sup>11</sup>

The Ayurveda Umbrella Association Germany (ADAVED) would like to point out that Ashwagandha has also been used successfully and safely in Europe for more than 40 years. At the same time, the ADAVED emphasises that the use of herbal remedies and dietary supplements should always be done responsibly and safely. In addition to purchasing from reputable sources (e.g. pharmacies, certified mail order companies), this also includes detailed preliminary information and/or counselling by medical professionals to clarify the advisability of taking the product.<sup>12</sup> It should be used in consideration of the individual state of health and after weighing up the benefits and risks. The ADAVED expressly advises against uncontrolled long-term use without a medical indication.

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<sup>1</sup> <https://www.bfr.bund.de/cm/343/ashwagandha-schlafbeeren-paeparate-mit-moeglichen-gesundheitsrisiken.pdf>

<sup>2</sup> <https://foedevarestyrelsen.dk/Media/638245843133059907/Withania%20somnifera%20%20risikovurdering%2015%20maj%202020.pdf>

<sup>3</sup> <https://www.bfr.bund.de/cm/350/risikobewertung-von-pflanzen-und-pflanzlichen-zubereitungen.pdf>

<sup>4</sup> <https://www.aerzteblatt.de/nachrichten/154212/Bundesinstitut-warnt-vor-Schlafbeerenpraeparaten>

<sup>5</sup> <https://ccras.nic.in/wp-content/uploads/2024/09/Revised-Ashwagandha-Booklet-9.8.2024-final.pdf>

<sup>6</sup> [https://iris.who.int/bitstream/handle/10665/42052/9789241547055\\_eng.pdf](https://iris.who.int/bitstream/handle/10665/42052/9789241547055_eng.pdf)

<sup>7</sup> [https://www.ema.europa.eu/en/documents/public-statement/final-public-statement-withania-somnifera-l-dunal-radix-first-version\\_en.pdf](https://www.ema.europa.eu/en/documents/public-statement/final-public-statement-withania-somnifera-l-dunal-radix-first-version_en.pdf)

<sup>8</sup> [https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/abgrenzung/Expertenkommission/stellungnahmen/2020-01.pdf?\\_\\_blob=publicationFile](https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/abgrenzung/Expertenkommission/stellungnahmen/2020-01.pdf?__blob=publicationFile)

<sup>9</sup> <https://ayush.gov.in/>

<sup>10</sup> <https://ccras.nic.in/wp-content/uploads/2024/09/Revised-Report-Safety-of-Ashwagandha.pdf>

<sup>11</sup> <https://ccras.nic.in/wp-content/uploads/2024/09/Ministry-of-Ayush-press-statement-ashwagandha.pdf>

<sup>12</sup> <https://ayurveda-dachverband.de/2024/06/17/sichere-und-qualitativ-hochwertige-ayurveda-produkte/>